GUIDANCE FOR INDUSTRY CONSULTATION

GN-12-2: Guidance on Grouping of Medical Devices for Product Registration – Device Specific Grouping Criteria

CONTENTS

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

Update Process for this Guidance Document

This version of GN-12 guidance document applies to all medical device registration applications submitted to HSA from 1 October 2015. The grouping criteria described in the GN-12-1 and GN-12-2 shall be strictly adhered to in submitting your medical devices for registration.

Any requests to reconsider or review these existing grouping criteria shall be submitted via email to hsa_md_info@hsa.gov.sg with subject header "Request for review of GN-12 grouping criteria". The email should include detailed information regarding:

(i) Device type and description
(ii) Existing grouping options and their limitations (if any)
(iii) Proposed grouping criteria and the rationale
(iv) Technical/scientific information to support the above proposal

Such requests received will be reviewed by HSA periodically and if deemed acceptable, the GN-12-1 and GN-12-2 guidance documents will be updated. Updating of the documents will only be done bi-annually (once in 6 months). Any new or revised grouping criteria shall be implemented only after these have been published online as revised versions of the GN-12-1 and GN-12-2 guidance documents.

REVISION HISTORY

Guidance Version	Revision
R1 ► GN-12-2: Revision 1 (draft)	R1

**Where applicable, changes and updates made in each document revision are annotated within the arrow symbol "►".*

1. INTRODUCTION

1.1. Purpose

This document is meant to provide device specific guidance in determining whether certain models of specific medical devices can be included together and submitted in one product registration application.

1.2. Background

Under the Health Products Act (*Act*), all medical devices to be supplied locally are required to be registered with HSA prior to supply.

In order to address the diverse categories of devices and the multitude of models of an individual device that may differ from one another incrementally, device specific grouping criteria have been developed and are presented in this GN-12-2 guidance document. The general grouping criteria described in the GN-12-1 guidance document are also applicable to these devices in addition to the device specific grouping criteria set out in this document. Applicants should determine and perform the grouping of medical devices to be registered based on GN-12-1 and GN-12 -2 guidance documents when preparing their medical device product registration submissions.

1.3. Scope

This document applies to medical devices for which specific grouping criteria have been described in this document.

1.4. Definition

Definitions, which are not set out in the *Act* and Health Products (Medical Devices) Regulations (*Regulations*), are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

ACCESSORY: for the purposes of this guidance document, means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose. An accessory is typically intended to be used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device.

PROPRIETARY NAME: for the purposes of this guidance document, a unique name given by the product owner to identify a medical device as a whole product, also known as the trade name or brand name.

INTENDED PURPOSE/INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

MEDICAL DEVICE: means a medical device as described in the First Schedule of the *Act.*

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means a person who —

(a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

2. GENERAL PRINCIPLES OF GROUPING

Medical devices that can be grouped into one of the grouping categories specified in the GN-12-1 and also in this GN-12-2 guidance documents can be submitted in one product registration application.

Grouping of medical devices is for the purpose of product registration submission. However, the listing of the medical devices on the Singapore Medical Device Register (SMDR) upon approval may differ from the initial grouping. For example, medical devices with different proprietary names or brand names may be submitted in one product registration application if they meet any of the grouping categories defined in the GN-12-1 or this GN-12-2 guidance documents. However, the devices with different proprietary names will be listed separately under different device listings on the SMDR.

Existing regulatory requirements apply to all medical devices to be registered, regardless of the manner in which they are grouped for product registration submission. Information on all medical devices within a grouping must be submitted as part of the requirements for registration, such as authorisation from all medical device product owners for registration and data to substantiate the performance of these devices within the grouping.

Only device models that are eventually listed on the SMDR shall be supplied on the market. The device listing information on the SMDR shall be determined as appropriate by HSA. For example, submissions with device groupings which allow for accessories from different product owners, only the product owner of the primary device will be listed on the SMDR, although the documentation relating to other product owners are required to be submitted as part of the registration submission. The final determination for the device listing information on the SMDR shall be made by HSA.

The Registrant shall undertake the following post-market duties and obligations for all medical devices and accessories registered on the SMDR registered by the Registrant or as part of grouped registrations (e.g. IVD TEST KIT, SYSTEM). This is regardless of whether these devices are from the same or different product owners:

- comply with the conditions applicable to the registered medical device and conditions imposed on the Registrant;
- submit applications to the Authority for changes made to the registered medical device;
- maintain records of supply;
- maintain records of complaints;
- report defects and adverse effects to the Authority; and
- notify the Authority concerning field safety corrective action (FSCA), including recall.

3. DEVICE SPECIFIC GROUPING OF CLASS A AND CLASS B DENTAL MEDICAL DEVICES USING DENTAL GROUPING TERMS FAMILY

Dental Grouping Terms (DGT) are collective generic terms used to describe a group of similar Class A and Class B dental medical devices with a common intended purpose.

A DGT grouping of dental medical devices is a collection of dental devices and each individual device:

- is from the same product owner ;
- within the risk classification of Class A or Class B; and
- intended purpose falls within the descriptor of one DGT

The product registration application may contain accessories of a lower risk class if they are specifically intended to be used together with the dental devices submitted under a DGT.

For Class A or Class B dental medical devices, the applicant may choose to group their dental devices using the general grouping criteria described in GN-12-1 guidance document or this device specific grouping criteria using the DGT for product registration. DGT is not applicable to Class C and Class D dental medical devices.

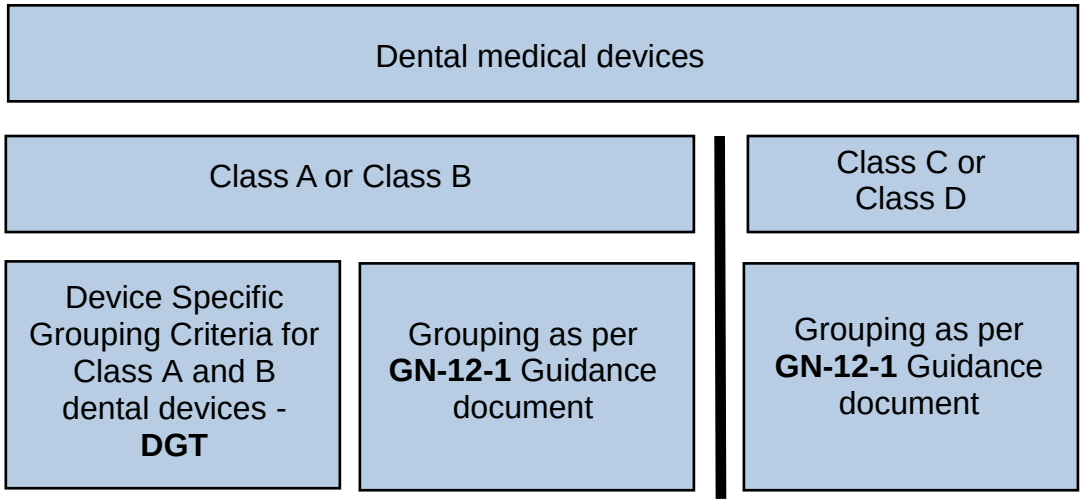


Figure 1 Dental medical device grouping consideration

When dental devices satisfy the above conditions to be grouped in one DGT application, the device name listed on the SMDR upon approval will be based on the dental grouping term used during product registration. The descriptor of the DGT will be used as the description of intended use on SMDR. The individual models will be listed on the SMDR as per product name (device label).

LIST OF DENTAL GROUPING TERMS (DGT) AND RESPECTIVE DESCRIPTORS

The list of DGT and respective descriptors are only applicable to Class A and Class B dental devices.

No	DGT	Definition
1.	Adhesive kit for dental composite	A collection of devices intended to be used to bond attachments such as hooks or buttons to the teeth and/or to an orthodontic aligner during dental or orthodontic teeth adjustment. The contents of this kit may include etchant, bonding resin, bonding paste, spatula, brushes, and a paper pad.
2.	Cryoanaesthesia device, dental	A dental brace-like device that is chilled to freezing/subfreezing temperatures and then applied to the labial sulci (gums) in a patient's mouth for a period to provide a cold anaesthesia for the underlying nerves. It is typically made of a thermoplastic elastomer (TPE) and cryogenic materials. This device may be used as a substitute for hypodermic drug delivery during dental procedures.
3.	Cryogenic spray, dental	A refrigerant typically contained in an aerosol dispenser and used to cool down a tooth by spraying on it, mainly to find out if the pulp is vital. It can also be used as a local anaesthetic when extracting deciduous teeth in children.
4.	Cusps, dental	A device designed to provide an artificial projection on the chewing surface of the tooth to achieve a proper bite.
5.	Dental abrasives	A dental material made from various base substances having some abrasive qualities [e.g., treated sodium bicarbonate (NaHCO3) or aluminium oxide (Al2O3)] and applied with an appropriate device (e.g., a dental abrasive air jet system) to the surface of teeth or dental devices. It has a wide variety of both prophylactic and treatment applications such as the removal of plaque and stains, cleaning fissures (above and below the gingiva), the preparation of a tooth surface prior to bonding, the cleaning of orthodontic appliances (bands and brackets), the removal of adhesive residue, and the cleaning of implants prior to loading. It includes accessories e.g. mixing pad, dispenser and other components required for dental abrasion.

6.	Dental adhesives/ primers	A material primarily used as a bonding promoting substance between dental materials. It does not include cements.
7.	Dental burs	A dental bur is a rotary cutting device designed to fit into a dental handpiece and intended to cut hard structures in the mouth, e.g. teeth or bone. It can also be used to cut hard metals, plastics, porcelains and similar materials.
8.	Dental caries detector, electrical impedance	A device designed to measure resistance to the flow of electric current across teeth for the diagnosis of early stage dental caries and/or to monitor the progress of caries (carious areas being less resistant due to higher concentrations of fluid). It typically consists of a probe with an electrode placed in contact with the tooth to be tested and a second counter electrode, separate from the probe, which is placed in contact with another part of the patient's body to complete an electrical circuit connecting the two electrodes; and an electronic control unit that quantifies the resistance. This procedure is also known as electronic caries monitoring/measurement (ECM).
9.	Dental caries detector, optical induced fluorescence	A device designed to determine the changes in the fluorescence of teeth enamel and dentine due to mineral loss, mainly for the diagnosis of early stage dental caries and/or to monitor the progress of caries. It consists of a light source (typically a laser) that elicits fluorescence in teeth, and a unit that quantifies the altered fluorescence of the carious tooth tissue.
10.	Dental caries removal solution	A liquid substance used in dentistry to detect and remove caries from an infected tooth.
11.	Dental casting materials	Compounds associated with the formation of a dental cast [i.e. a positive copy of a part of the oral anatomy made in an impression (mould)].
12.	Dental cavity liner	A substance intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth from chemical irritation. The device is typically a thin layer of zinc oxide (ZnO) and eugenol (C10H12O2), or calcium hydroxide (Ca(OH)2).

13.	Dental cement	Compounds used in dentistry/ orthodontics typically to bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It includes accessories e.g. mixing pad, dispensor and other components required to complete the cementing procedure.
14.	Dental cement kit	A collection of components designed to complete a cementing procedure.
15.	Dental crowns/ bridges	Solid blocks or liquid materials used to manufacture partial or full crowns and bridges.
16.	Dental dry field device	A pre-assembled device used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It forms a frame around the oral cavity and provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of cheek retractors, a tongue guard, suction adaptors, and tubing with Y-piece connection to a suction system.
17.	Dental dry field kit	A collection of devices used in orthodontic and restorative dentistry to maintain a dry oral cavity for treatment procedures. It provides the operator with easy access to the field of operation by holding the mouth open, displacing the tongue, and removing saliva during various procedures (e.g., bonding orthodontic brackets, bleaching, applying veneers or pit and fissure sealants, posterior restorations). It typically consists of bite blocks, pad extenders, suction tips of varying sizes, and tubing that connects to a suction system.
18.	Dental etching composite	A device, typically in form of solution or gel, used to create a retentive surface for a composite, an adhesive or a pit and fissure sealant.
19.	Dental implant debridement brush	A rotary dental instrument designed for the debridement of a patient's dental implants affected by peri-implantitis; a destructive inflammatory process of the soft and hard tissues surrounding dental implants. It is a brush-like device, typically consisting of titanium bristles at the distal end of a high-grade steel shaft, that is held in a dental handpiece which provides its rotation for the mechanical removal of biofilm from the surface of the implants. This is a single-use device.

20.	Dental implant extractor	A manually-operated, dental device used to retrieve a dental implant, typically because of damage (e.g., a broken collar) or malfunction, from the oral cavity. It is typically made of toughened, high-grade steel and has a cylindrical design with a coarse, left-handed fluting with a steep pitch that spirals up the tapered working end and a hexagonal head at the proximal end that fits a torque wrench socket. Such a device is inserted into the implant to be removed and turned anticlockwise (counterclockwise). The anticlockwise torque exerted makes this device grip into the implant, which is then unscrewed. It is a single-use device.
21.	Dental implant, accessories	Device designed to provide support and a means of retention for a dental prosthesis (e.g., bridge, single-tooth, overdenture) during surgical placement of a dental implant into alveolar and/ or basal bone of the mandible or maxilla.
22.	Dental implant, prosthetic teeth bar	A small rod, usually cast or brazed, that bears prosthetic teeth and allows them to be attached to the dental implant abutments.
23.	Dental implant, suprastructure	A prefabricated device that is incorporated into, or creates, a suprastructure on dental implants to mimic preparations of natural teeth. It is used during dental implant restorative procedures. It typically includes burnout/temporary cylinders, fixture impression pick-ups, replica devices.
24.	Dental implant/prosthesis, surgical procedure kit	A collection of various dental instruments designed for the surgical placement of dental implants or prostheses. It does not contain pharmaceuticals. It typically contains various dental drills (drill bits), drill extensions, depth gauges, wrenches and torque wrench, screwdrivers, forceps, trays and osteotomes.
25.	Dental precision attachments	Dental devices designed for attaching a fixed or removable prosthesis to the crown of an abutment tooth, dental restoration (including implants), or dental appliance.
26.	Dental procedure console and accessories, hydraulic	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). The system is powered by pressurized water via a connecting hose to the handpiece/motor water-driven turbine.

27.	Dental procedure console and accessories, line-powered	An assembly of devices designed to bore/excavate bones, teeth, and tough tissues during a dental surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, polishing disks). This system is electrically-powered, typically from the mains and supplies the handpiece/motor with low-voltage electricity (through a control unit.
28.	Dental procedure console and accessories, pneumatic	An assembly of devices designed to bore/excavate bones and tough tissues during a surgical procedure. It typically consists of a motorized drill handpiece and/or motor, a control unit, and a variety of attachments used to hold the drilling/excavating instruments (e.g., drills, burs, screwdriver bits). The system is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece/motor.
29.	Dental procedure handpiece, hydraulic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. The device incorporates a small water-powered turbine motor that is driven by a source of pressurized water; it will typically have a built-in water spray for cooling the rotating instrument. It is typically connected to a dental delivery system or a free-standing independent system.
30.	Dental procedure handpiece, line-powered	A mains electricity, hand-held, dental device that includes a chuck or collet for attaching a dental drill, bur, reamer, and other similar rotating instruments used in dentistry to bore/excavate bones, teeth, and tough tissues. It is powered by a low-voltage electric micro-motor that is an integral part of the device. It is typically connected through the dental delivery system or a free-standing independent control unit.
31.	Dental procedure handpiece, pneumatic	A hand-held dental device that includes a chuck for attaching dental drills, burs, reamers, and similar rotating instruments used to bore/excavate bones, teeth, and tough tissues in dentistry. It will typically include a built-in motor. The device may be cannulated to allow for use of a guidewire and may be of the micro or macro design. It is pneumatically-powered (gas-powered) by either nitrogen (N2) or surgical-grade air via a connecting hose to the handpiece.

32.	Dental pulp testing electrode gel	An electrode gel for pulp testers is a device intended to be applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.
33.	Dental pulp-capping material	A dental compound designed to cover an exposed or nearly-exposed dental pulp (e.g., due to deep cavities) to provide protection against external influences and to promote healing. This compound does not have dental cement or dental cavity liner intended uses. This is a single-use device.
34.	Dental reinforcing fibre	A device used in general restorative dentistry and orthodontic treatment typically as reinforcement of dental polymer-based materials, used for the construction of dental prostheses, i.e., splints, posts, crowns, and bridges. This device is typically made of polyethylene fibres supplied in strands, braid, or ribbon in a variety of sizes. It may also be used for the stabilization of avulsed teeth maintaining diastema closures or split-tooth syndrome. The fibres increase the strength of composite materials, and provide improved safety by assisting in the retention of pieces in the event that a dental prosthesis is broken. This is a single-use device.
35.	Dental restorative / cavity varnish	A liquid substance used to cover dental filling material in the initial setting period after application typically to prevent moisture infiltration, especially when a dental silicate or glass ionomer cement is used as a filling material. The device typically consists of dissolved artificial resins. It is used for the protection of pulpal tissue and to provide a marginal seal to newly placed amalgam restorations.
36.	Dental restorative/ repair materials	Liquid compounds specially designed to fill dental cavities, seal pits and fissures, restore damaged dental tissues, or for inlays, onlays and veneering. It includes accessories that are used specifically with the materials. It includes accessories e.g. mixing pad, dispenser and other components required to complete the restorative procedure. It does not include obturation of root canal.
37.	Dental restorative/ repair kit	A collection of devices designed to fill dental cavities or restore dental tissues. It does not include obturation of root canal.

38.	Dental retention pin	A device intended to be placed permanently in the tooth to provide retention and/or stabilization for a dental restoration, e.g. a filling or a crown. It is typically made of stainless steel or titanium and comes in a variety of sizes. The device is inserted into a pre-drilled hole in the tooth and is secured by threading, friction and/or cementing.
39.	Dental retention pin kit	A collection of various dental instruments, devices and materials intended for the insertion of permanent pins in healthy dentin to provide retention and/or stabilization of dental restorations, e.g. fillings and crowns. It is presented as a kit and contains, e.g. retention pins of incrementing sizes, a selection of dental drills, and the necessary instruments to facilitate the procedure.
40.	Dental scalers, pneumatic	Scaler tip/inserts which may consist of handpiences that are designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. Water is also fed through the handpiece and attached tip to assist in the process. It is typically designed to connect to an existing air driven handpiece tubing and the water spray for lavage.
41.	Dental scalers, rotary	Scaler tip/inserts which may consist of handpieces, intended to be attached to a powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy.
42.	Dental scalers, ultrasonic	Scaler tip/inserts (which function as part of an ultrasonic scaler system) which may consist of handpieces that together transmit ultrasonic energy from a generator to the oral cavity for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. Water or a rinsing solution (e.g., chlorhexidine) is also fed through the handpiece and attached tip to assist in the process. This device is typically designed with permanently attached cables in the form of a pen or pencil.

43.	Dental scaling system, pneumatic	An assembly of devices designed to use compressed air to generate a vibrating action at its point of patient contact for the removal of accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. It typically consists of a scaler handpiece and self-locking, removable tip. The handpiece may connect to an existing air driven handpiece tubing and the water spray for lavage. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
44.	Dental scaling system, rotary	An assembly of powered dental handpiece that provides rotation and is used to remove calculus deposits and other accretions from tooth surfaces during dental cleaning and periodontal (gum) therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
45.	Dental scaling system, ultrasonic	An assembly of devices that uses ultrasonic energy at its point of patient contact to remove accretions from tooth surfaces during dental cleaning or periodontal (gum) therapy. It typically consists of an energy-generating unit [which may contain a water or rinsing solution (e.g., chlorhexidine) source], a handpiece with connecting cable, an insert tip (the distal end of the system used in the oral cavity), and a foot control. This device is used for procedures that may involve the removal of plaque, biofilm, or gross calculus from shallow to deep periodontal pockets. It can be also used for the removal of orthodontic cement.
46.	Dental sealants, endodontic	A prefabricated, solid dental substance used in endodontics to fill or permanently obturate the root canal of a tooth. The substance may set without assistance of moisture, and is typically intended for orthograde use (i.e., a root filling placed from the coronal aspect). The device has various metallic or polymeric compositions that include, but are not limited to, silver (Ag), methylmethacrylate, zinc oxide eugenol, glass alkenoate, and calcium hydroxide (Ca(OH)2).

47.	Dental sealants, pit/fissure	A resin-based dental material suitable for sealing pits and fissures on teeth. It may be chemically cured or external energy cured. It may include accessories e.g. mixing well, brush etc or other components required to complete the sealing procedure.
48.	Dental shaded pontic kit	A collection of devices intended to be used to produce artificial tooth veneers (shaded pontics) typically inside clear plastic custom-made teeth aligners (retainer-style orthodontic appliances). This is used to create the appearance of teeth inside the aligner to cover spaces where teeth may be missing for aesthetic and/or therapeutic purposes during treatment to realign teeth. The contents of the device may include polymer-based materials, dispenser gun, mixing tips, applicator brushes and practice aligner.
49.	Dental solution, scaling	A liquid substance used in dentistry to soften and partially solubilize a dental calculus (a hard deposit that forms on the teeth) before scaling mechanically so that less force is required, especially when teeth are loose. It will typically contain acid as a solvent (e.g., hydrochloric) and include other elements (e.g., iodine and excipients).
50.	Denture clasps	Dental devices designed to retain and stabilize removable partial dentures to stationary teeth.
51.	Denture reliners	A device consisting of polymer based material, e.g. plastic resin, that is applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. Denture relining is defined as a process of providing a new fitting surface to a denture.
52.	Facebow	A caliper-like dental instrument used to record the relative position of the maxillary arch to the temporo-mandibular joint (TMJ), or the opening axis of the jaw. It is used to orient dental casts in the same relationship to the opening axis of the articulator.
53.	Fixture/appliance dental drill, single-use	A shaft of metal (a drill bit) intended to be used in dental surgery to create channels of appropriate depth and diameter in bone (osteotomy) of the oral cavity to facilitate the implantation of a dental fixture/appliance. It is typically made of a high-grade stainless steel alloy. The device is typically available in a set of graduated sizes and various forms and functions (e.g., guide, pilot, twist, cortical, conical). It is attached to a motorized handpiece or other power source that provides rotation. This is a single-use device.

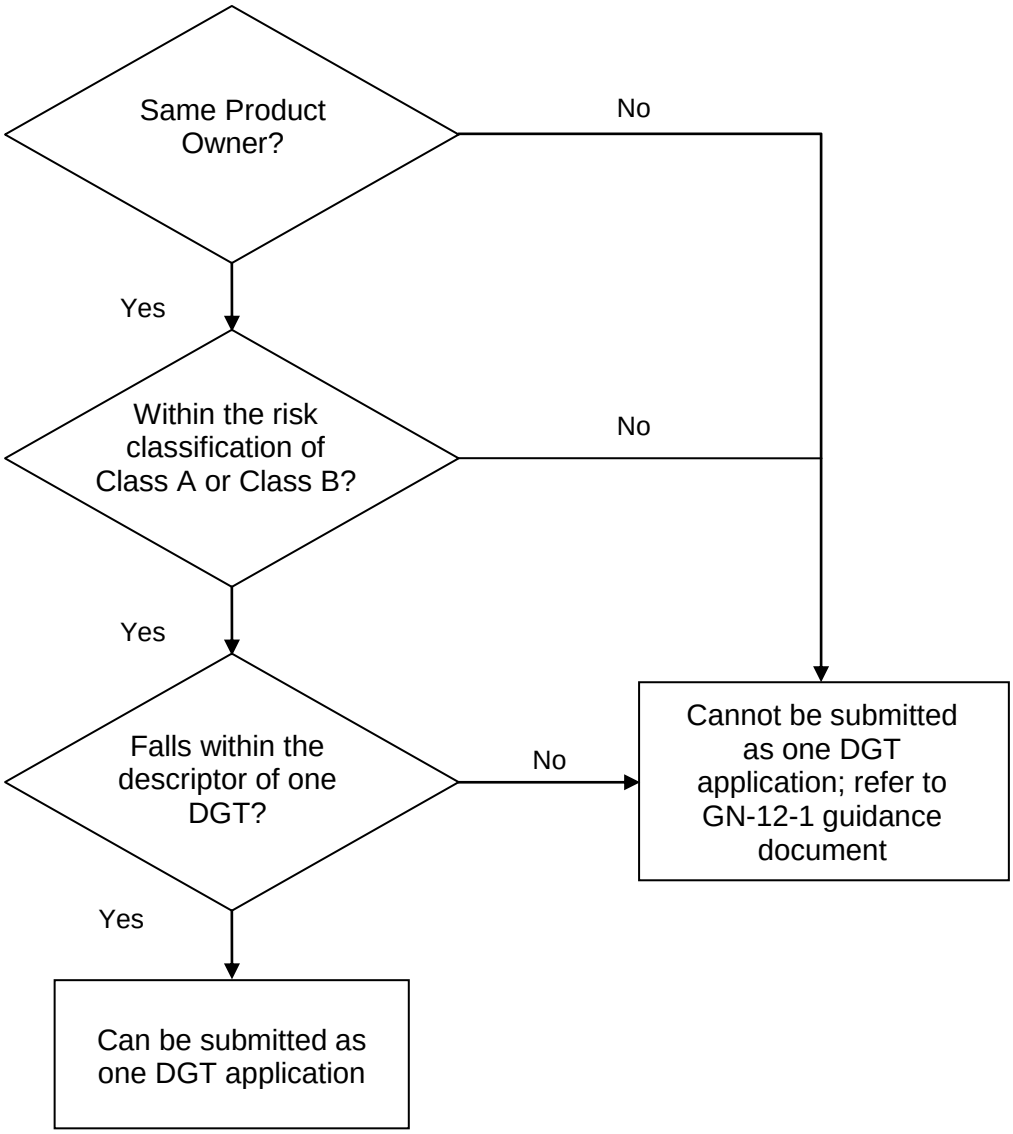
54.	Gingiva bleaching protector	A paste or gel-like substance designed to protect a patient's gums from the hydrogen peroxide found in teeth whitening agents used during chairside light-curing bleaching of the teeth. It is typically supplied in a disposable syringe and is applied with an applicator along the gingiva leaving the teeth exposed for treatment.
55.	Gingival retraction cord, non-medicated	A non-medicated, cotton string used to temporarily hold off the gingiva during abutment preparation.
56.	Gingival retraction kit	A collection of dental instruments and other items used to hold off the gingiva during abutment preparation.
57.	Gingival retraction solution	A liquid substance used in dentistry to induce gingival retraction by in situ impregnation of a non-medicated gingival retraction cord. It induces contraction of the upper strata of the free gingiva. This device may also induce a local stasis of gingival exudates and gingival haemorrhages.
58.	Non-medicated dental surgical procedure kit, single-use	A collection of various dental instruments, dressings and the necessary materials used to perform a dental surgical procedure. It does not contain any pharmaceuticals. This is a single-use device.
59.	Oral wound dressing, non - animal/ microbial-derived	A compound intended as a protective cover for the oral mucosa to manage wounds and sores in the mouth. It is used for various types of dental wounds, sores and lesions caused by dental prostheses/orthodontic braces; it may also be used to treat mucosal irritations/inflammation, dryness and gingivitis. It is supplied in various forms (e.g., gel, paste, fluid, spray solution of water/oil). It is normally available over-the-counter (OTC) for use in healthcare facilities or home. It is not derived from animal or microbial sources. This does not include pharmaceuticals.
60.	Orthodontic appliance archwire-cooling device	An instrument used in orthodontic dentistry to intra-orally chill or cool thermally-activated archwires when placing bends in an orthodontic appliance. The device, after it has been precooled (typically with a cryogenic spray), is applied to a desired point of contact on the wire to extract heat and allow easy bending. As the archwire warms to body temperature it attempts to return to its former shape, and thus contributes to the application of forces within the mouth. The device is typically formed as a heavy-duty stainless steel rod with an insulated plastic handle and a slot at the distal end to accept wire.

61.	Orthodontic appliances	Dental devices designed to influence the shape and/or function of the stomatognathic system through the application of physical force. It includes orthodontic anchor plate, orthodontic anchoring screw, orthodontic archwire, orthodontic archwire/bracket fixation ring, orthodontic bands, orthodontic brackets, orthodontic bracket adhesive, orthodontic clasps, orthodontic chin cap, orthodontic extraoral headgear, orthodontic face bow, orthodontic ligature, orthodontic magnet, orthodontic spring, orthodontic tube, orthodontic wire.
62.	Orthodontic space maintainer	A dental prosthetic replacement for prematurely lost deciduous teeth intended to prevent closure of the space before eruption of the permanent successors. Often an urgent necessity in the buccal segment to prevent impaction of the permanent teeth and other complications.
63.	Periodontal dressing, non - animal/ microbial-derived	A dental material in paste form which is placed over the periodontal tissues as a dressing, normally after surgery. It is not derived from animal or microbial sources. This does not include pharmaceuticals.
64.	Root canal filling-removal solution	A liquid substance used in endodontic procedures for the softening and removal of root canal fillings. It will typically be introduced into the root canal using instruments. The device typically contains solvents and other elements (e.g., tetra chloroethylene, formamide, eucalyptol, excipients).
65.	Root canal irrigation/ rinsing solution	A substance used in dentistry to facilitate cleansing/irrigation of the root canal (the canal space) during and/or after endodontic instrumentation for the removal of the smear layer, pulpal tissue, necrotic materials, and bacteria from the instrumented root canal, before placement of the endodontic filling. It is typically available as an aqueous solution delivered into the canal with an irrigation needle or similar device, providing mechanical and possibly chemical cleansing of the canal.
66.	Root canal obturation kit	A collection of dental devices, synthetic materials, and solutions designed to permanently prime, seal, and/or fill a tooth undergoing a root canal procedure. This device typically includes materials such as a primer (for bonding to the walls of the canal), a sealer (for bonding to the primer), and endodontic points and pellets (for the filling). This bonding process creates a monoblock filling resulting in increased resistance to bacteria penetration and fracture for root canal-treated teeth.

67.	Root canal post kit	A collection of root canal posts and devices used for the insertion of root canal posts. These are typically prefabricated and made in a variety of shapes, dimensions and materials, e.g., they can be non-threaded, pre-threaded, or self-tapping, straight or tapered, and made of alloy, ceramic and fibre reinforced polymers. This device typically includes the root canal posts, drills and thread cutter.
68.	Root canal posts	A dental device (rod) intended to be inserted and cemented into a prepared root canal of a tooth to stabilize and support a restoration. Pre-fabricated root canal posts come in various shapes, dimensions, and materials, e.g. metal, fibre reinforced polymer and ceramic.
69.	Root surface conditioner	A dental material, typically of neutral pH, used for topical application on exposed/scaled root surfaces for the removal of the smear layer (adherent debris produced when cutting the enamel or dentin in cavity or endodontic preparation, Circa 1 micron thick) during dental/periodontal surgery. The material is removed (washed off) after the recommended period to expose the collagenous matrix of dentine surfaces. It is typically presented in the form of a gel and consists of, e.g., edetate disodium (EDTA) and carboxymethylcellulose (CMC) with a neutral pH.
70.	Tooth preservation kit	A collection of devices designed to preserve and transport a tooth that has been knocked out (i.e., avulsed) so it can be reimplanted. It typically includes instruments, preserving solutions, a container (e.g., a vial or cup with a plastic net inside to hold the tooth suspended in the preservation solution), and swabs/bandages. It is used to avoid tooth cell crushing and/or dehydration by immersing the tooth in a pH balanced solution compatible with periodontal cells, and is typically used in field emergency situations after traumatic knock out of teeth.
71.	Warm-bonded endodontic obturation system	An assembly of devices designed to deliver preheated resin-based sealing, filling, and core materials into a root canal for direct warm bonding during an endodontic obturation procedure. It typically consists of a mains electricity oven specifically used to heat the preloaded oburators, a series of root canal sizers (verifiers) used for the selection of the appropriate obturator, and preloaded obturators; other materials may be included (e.g., self-etch sealer).

72.	Denture base resins	A polymer-based dental material used for the fabrication of a denture base (the portion of a complete or removable partial denture which rests on the oral mucosa and retains the artificial teeth) or repair of a denture. This is a single-use device.
73.	Dental disinfectants	A substance, typically in liquid, wipes or powder (reconstituted in water) form that destroys harmful microorganisms or inhibit their activity on medical devices which are specific for dental purposes or for use in dental procedures. It is not intended for disinfection as end point of processing. The medical device is typically bathed by the substance for a specified period of time, or the substance is sprayed on, or manually applied to the medical device, in order to achieve disinfection.
74.	Dental suction system cannula, single-use	A semi-rigid or rigid hollow tubular component of a dental suction system designed to be inserted into the oral cavity for the aspiration and removal of blood, pus, saliva, debris, and water during a dental procedure. This is a single-use device.

Decision Flowchart for Grouping of Dental Medical Devices using Dental Grouping Terms (DGT)



The following examples provide a comparison between the grouping of dental medical devices using the general grouping criteria in GN-12-1 guidance document and using the device specific grouping - DGT.

Example:

Product Owner "HSA Zen" manufactures 3 different dental cements of different cement materials as follows:

Product name	Description
HSA Zen 1 dental cement	Main Constituent: Zinc Phosphate Available as 2g and 4g syringes
HSA Zen 2 dental cement	Main Constituent: Polycarboxylate Available as 2g syringe and 2g kit (dispenser, etchant, adhesive, primer)
HSA Zen 3 dental cement	Main Constituent: Glass Ionomer Available as 2g and 4g syringes

<u>Using the general grouping criteria in GN-12-1</u>

Based on general grouping criteria in GN-12-1 guidance document, these 3 products cannot be grouped together as a FAMILY because the difference amongst the products (material) is not within the scope of permissible variants.

<u>Using device specific grouping - DGT</u>

In order to submit a product registration using the device specific grouping criteria in GN-12-2 guidance document - DGT, the applicant has to determine if the dental medical devices fulfill the DGT requirements:

Same product owner	**Yes** ("HSA Zen" is the common product owner)
Within the risk classification of Class A or Class B?	**Yes** (all products are Class B medical devices)
Falls within the descriptor of one DGT	**Yes;** all 3 products fall under the DGT of : **DGT - Dental Cement** <u>*Descriptor for Dental Cement*</u>: Compounds used in dentistry/ orthodontics typically to

	bond a dental prosthesis to the anatomy (luting agent), to form an insulating layer under dental restorations. It includes accessories e.g. mixing pad, dispenser and other components required to complete the cementing procedure.

Therefore, these 3 Class B dental cements, of different materials, can be grouped together in one application using the DGT "Dental Cement". Devices will be listed on SMDR as "HSA Zen Dental Cements".

Addition of New Models to a DGT Listing on the SMDR

The addition of new models to an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new models being added fulfill the device specific grouping criteria to be grouped using the same DGT. Registrant can submit a Change Notification if all DGT requirements are met. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

4. DEVICE SPECIFIC GROUPING OF HEARING AIDS

This section applies only to Class B hearing aids and excludes implantable hearing devices.

Generally, hearing aids can be categorised based on:

- Design (i.e Behind the ear (BTE) vs In the ear (e.g. al components of the hearing aids are contained in tiny case shell that fits in the ear or canal))
- Technology for sound amplification (i.e. analogue vs digital)
- Communication technology (i.e Wireless vs Non-wireless communication)

A device specific grouping of hearing aids comprises of a collection of hearing aids that are:

- from the same product owner;
- within risk classification Class B (hearing aids not including the implantable hearing devices);
- have the same design type (i.e. behind the ear **or** in the ear);
- have the same technology for sound amplification (i.e. analogue **or** digital); and
- have the same communication technology (i.e. wireless **or** non-wireless)

The product registration application may contain accessories of a lower risk class if they are intended to be used together with the hearing aids.

For Class B hearing aids, the applicant may choose to group their devices using the general grouping criteria described in GN-12-1 guidance document or this device specific grouping criteria for hearing aids or devices. This device specific grouping criteria for hearing aids would not be applicable for Class C and Class D medical devices (e.g. cochlear implant systems), as well as Class B hearing devices that are used in conjunction as part of an implantable hearing system (e.g. sound processors of a bone-anchored hearing system).

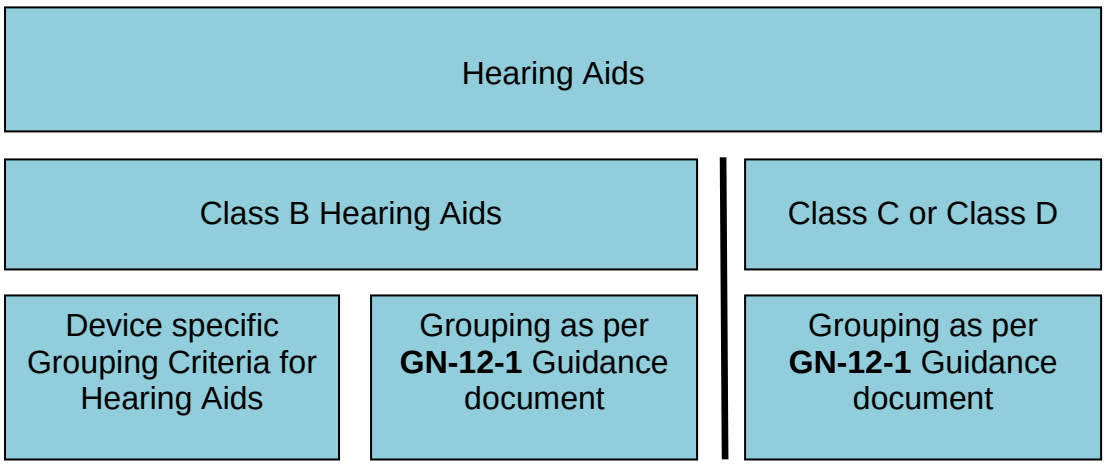
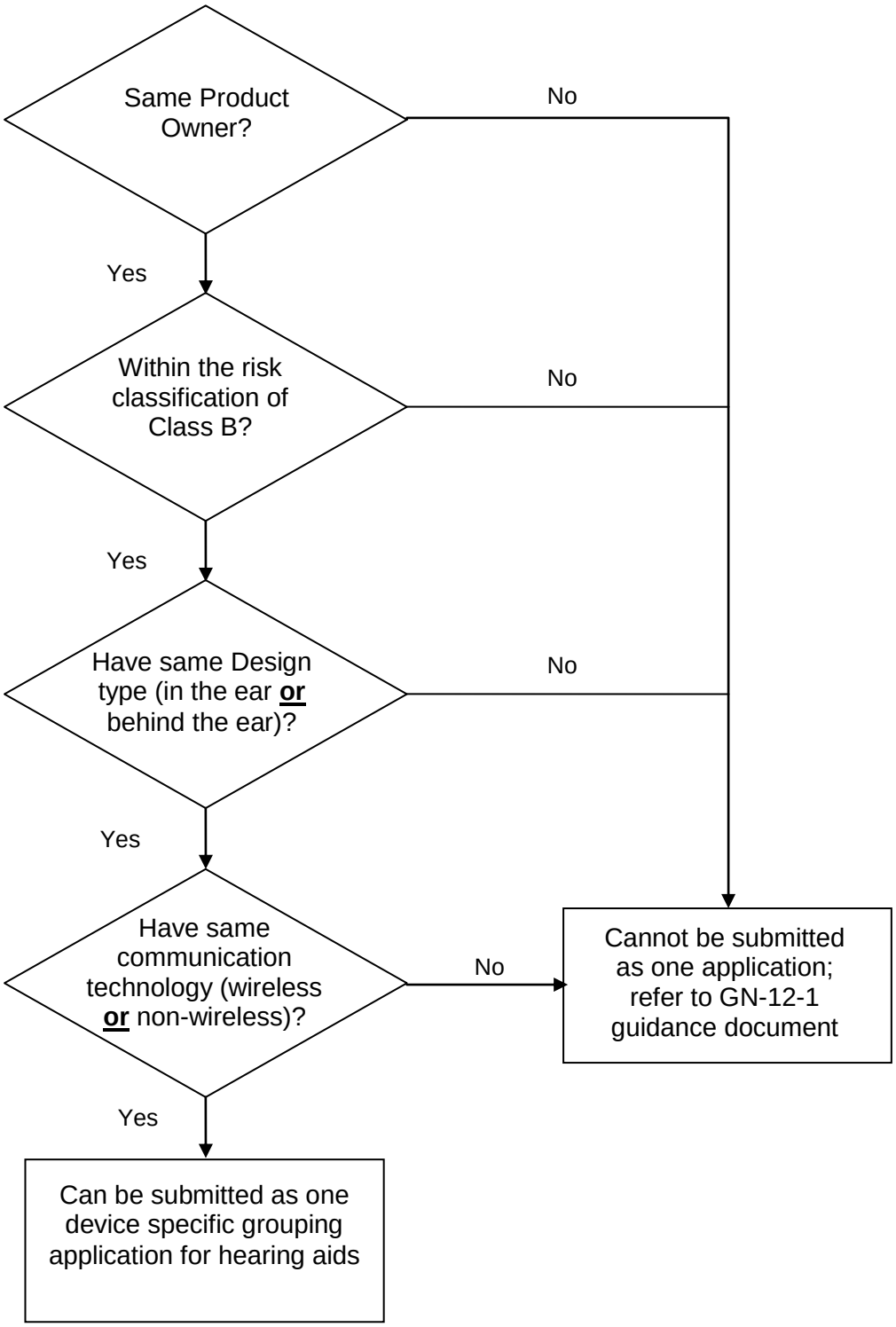


Figure 2 Hearing Aid grouping consideration

When hearing aids satisfy the above conditions to be grouped in one device specific hearing aid grouping application, but have different device proprietary names or brand names, the devices will be listed separately on the SMDR based on their proprietary names upon approval of the application.

Decision Flowchart for Grouping of Hearing Aids



Examples:

Case 1: BTE (behind the ear) and ITE (in-the-ear) hearing aids

Based on device specific grouping of hearing aids: Cannot be grouped together as they are of different design types hearing aids

Case 2: ITE (in-the-ear), ITC (in-the-canal) and CIC (completely-in-the-canal) hearing aids.

Based on device specific grouping of hearing aids: Can be grouped together as they are of similar design type of hearing aids

Addition of New Models to a Hearing Aid Listing on the SMDR

The addition of new hearing aids to an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new models being added carry the same device proprietary as the SMDR-listed devices. Although, the new models of the hearing aids satisfy the criteria to be grouped with the registered models, a new product registration application has to be submitted for the registration of these new models. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

5. DEVICE SPECIFIC GROUPING OF IMMUNOHISTOCHEMISTRY IN VITRO DIAGNOSTIC REAGENTS

Immunohistochemistry (IHC) IVD reagents are *in vitro* diagnostic (IVD) products consisting of polyclonal or monoclonal antibodies labelled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens, which excludes reagents specifically intend to be used with flow cytometry. This section applies to IHC IVD reagents and their accessories only.

A device specific IHC IVD grouping category comprises of a collection of IVD reagents and their accessories that are:

- from the same product owner;
- within the risk classification of Class B or Class C;
- based on IHC methodology; and
- within the same IHC IVD Grouping Category as listed below

When IHC IVD reagents and their accessories satisfy the criteria to be grouped under one of the six prescribed IHC IVD grouping categories, they can be submitted in one product registration application. However, the listing of the IHC IVD reagents and their accessories on the SMDR upon approval may differ from the initial grouping. The device name listed on the SMDR upon approval will be based on the IHC IVD grouping category used during product registration. The individual models will be listed on the SMDR as per product name (device label). Alternatively, the product owner and their applicants may choose to group these devices using the general grouping criteria described in GN-12-1 guidance document.

If any reagent and their accessories are intended for multiple usage categories such that it can be grouped in more than one IHC IVD grouping category, the applicant can choose to group the reagents and their

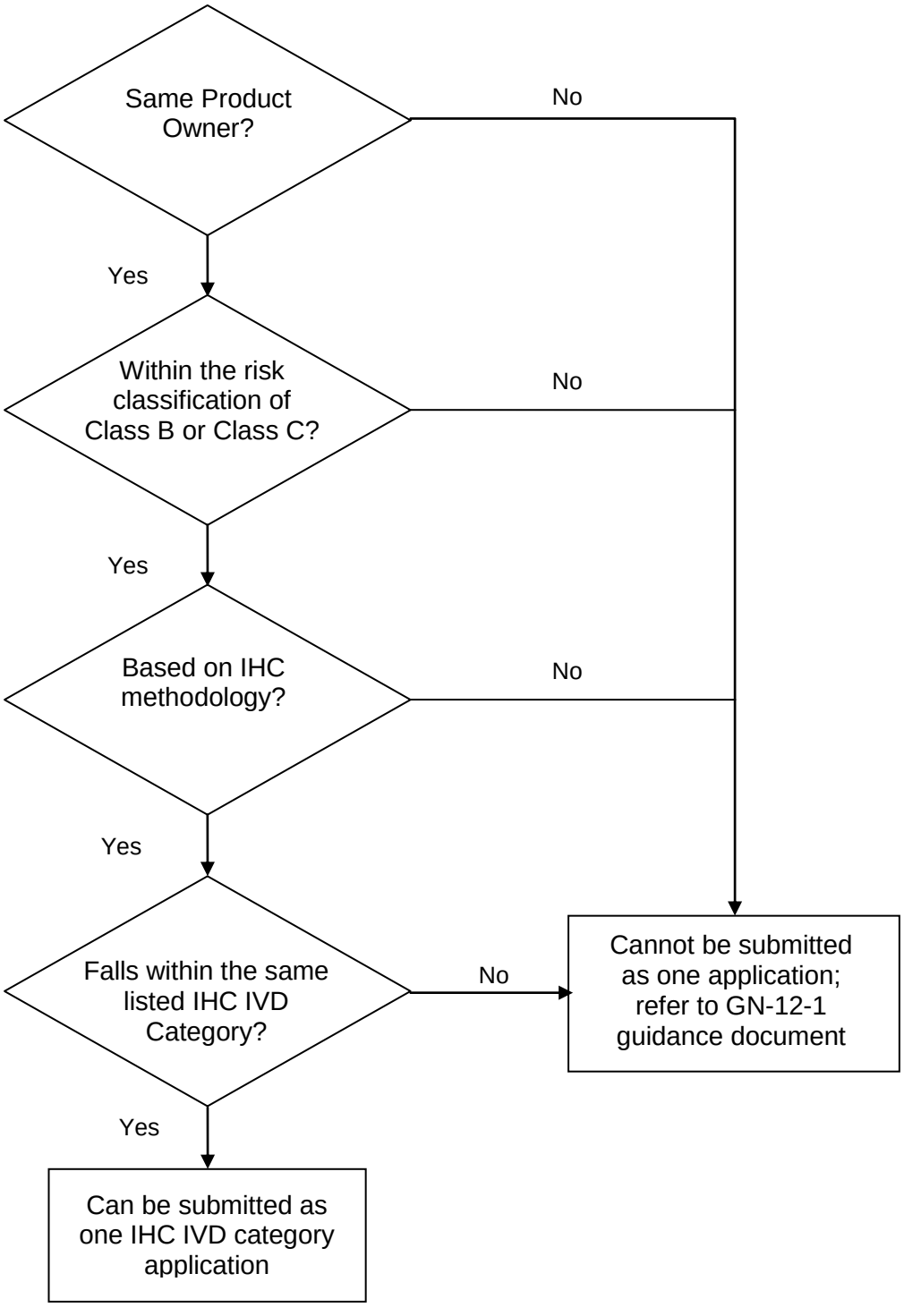
accessories as part of any one of the IHC IVD categories it qualifies. Information to support the intended purposes of all the reagents and their accessories must be submitted as part of the product registration application.

LIST OF IHC IVD GROUPING CATEGORIES

The list of IHC IVD categories for the device specific grouping of Class B and Class C IHC reagents and their accessories is a closed and positive list.

S/N	IHC IVD Grouping Category (closed list)	Examples of Analytes (non-exhaustive list)
1	Selective Therapy	(i) HER2/neu (ii) EGFR
2	Hematologic Disorder and Blood Cancer Markers	(i) Immunoglobulin Kappa chain (ii) Immunoglobulin Lambda chain
3	Other Cancer Markers	(i) Alpha fetoprotein (AFP) (ii) Cytokeratins (iii) CD117
4	Pathogen Markers	(i) Escherichia coli (ii) Candida albicans (iii) Herpes simplex virus protein VP22
5	Immune Disorders	(i) Anti-nuclear antibodies (ANAs) (ii) Anti-topoisomerase (iii) Organ-specific autoantibodies (iv) Anti-Streptococcal Hyaluronidase (v) Anti-Streptokinase (vi) Anti-Streptolysin O (vii) C-Reactive Protein
6	Other Pathology Markers	(i) P57 (ii) Growth hormone

Decision Flowchart for Grouping of Class B and Class C IHC IVD Grouping Category



Examples:

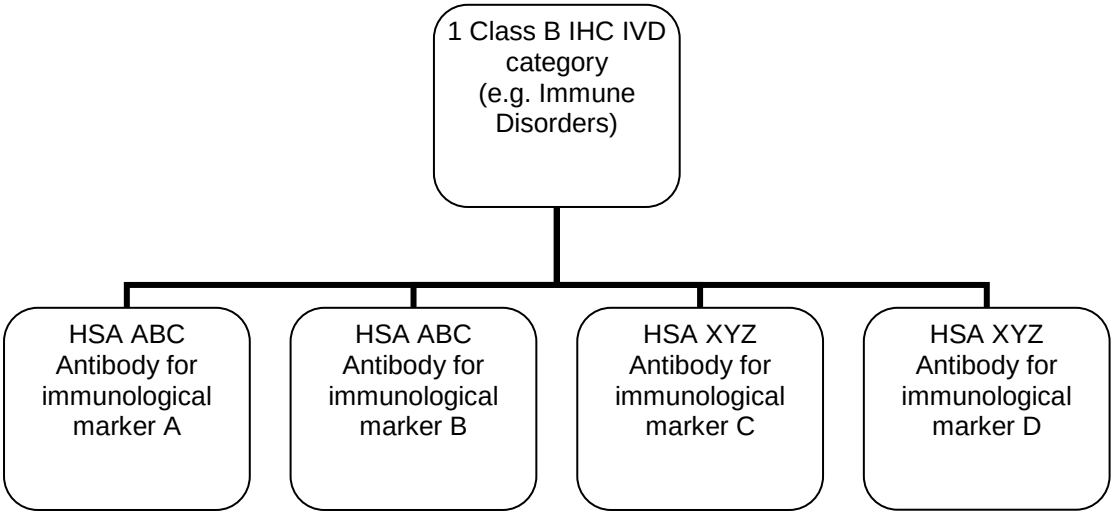


Figure 3 Example of a Class B IHC IVD grouping category

Based on the example provided in Figure 3, the four IHC IVD products qualify for submission as one IHC IVD grouping category and would result in two SMDR listings:

1. HSA ABC Immunohistochemistry Antibody (Immune Disorders)*
2. HSA XYZ Immunohistochemistry Antibody (Immune Disorders)**

* HSA ABC Antibody for immunological markers A and B are under one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA XYZ Antibody for immunological markers C and D are under one listing in which HSA is the product owner and XYZ is the proprietary name.

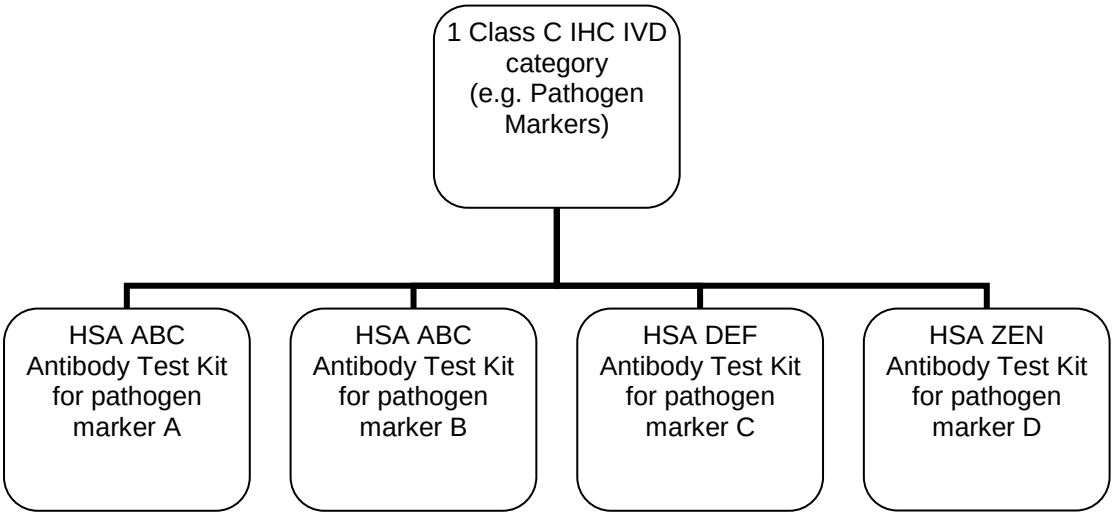


Figure 4 Example of a Class C IHC IVD grouping category

Based on the example provided in Figure 4, the four IHC IVD products qualify for submission as one IHC IVD grouping category and would result in three SMDR listings:

1. HSA ABC Immunohistochemistry Antibody Test Kit (Pathogen Markers)*
2. HSA DEF Immunohistochemistry Antibody Test Kit (Pathogen Markers)**
3. HSA ZEN Immunohistochemistry Antibody Test Kit (Pathogen Markers)***

* HSA ABC Antibody Test Kit for pathogen markers A and B are under one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA DEF Antibody Test Kit for pathogen marker C is under one listing in which HSA is the product owner and DEF is the proprietary name.

*** HSA ZEN Antibody Test Kit for pathogen marker D is under one listing in which HSA is the product owner and ZEN is the proprietary name.

Addition of New Models to an IHC IVD Grouping Category Listing on the SMDR

The addition of new IHC IVD products to an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new models being added fulfill the device specific grouping criteria (i.e. from the same product owner with the same proprietary name, of the same risk class and within the same IHC IVD grouping category) and carry the same device proprietary name as the SMDR-listed medical devices. Although, the new medical devices satisfy the device specific criteria to be grouped as an IHC IVD grouping category with the registered devices, a new product registration application has to be submitted for the registration of these new devices. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

6. DEVICE SPECIFIC GROUPING OF FLUORESCENCE IN SITU HYBRIDISATION PROBES IN VITRO DIAGNOSTIC REAGENTS

Fluorescence in situ hybridization (FISH) probes are *in vitro* diagnostic (IVD) products that allow for the detection and localisation of the presence or absence of specific DNA sequences on chromosomes, whereby the hybridisation of the probes with the DNA site will be visible using fluorescence microscopy.

A device specific grouping of FISH probes IVD grouping category comprises of a collection of IVD reagents and their accessories that are:

- from the same product owner;
- within the risk classification of Class B or Class C;
- based on FISH methodology; and
- within the same FISH probes IVD Grouping Category as listed below

When FISH Probes IVD reagents and their accessories satisfy the criteria to be grouped in one of the six prescribed FISH Probes IVD grouping categories, they can be submitted in one product registration application. However, the listing of the FISH Probes IVD reagents and their accessories on the SMDR upon approval may differ from the initial grouping. . The device name listed on the SMDR upon approval will be based on the IHC IVD grouping category used during product registration. The individual models will be listed on the SMDR as per product name (device label). Alternatively, the product owner and their applicants may choose to group these devices using the general grouping criteria described in GN-12-1 guidance document.

If any reagent and their accessories are intended for multiple usage categories such that it can be grouped in more than one FISH probes IVD grouping categories, the applicant can choose to group the reagent and their accessories as part of any one of the FISH probe IVD categories it qualifies.

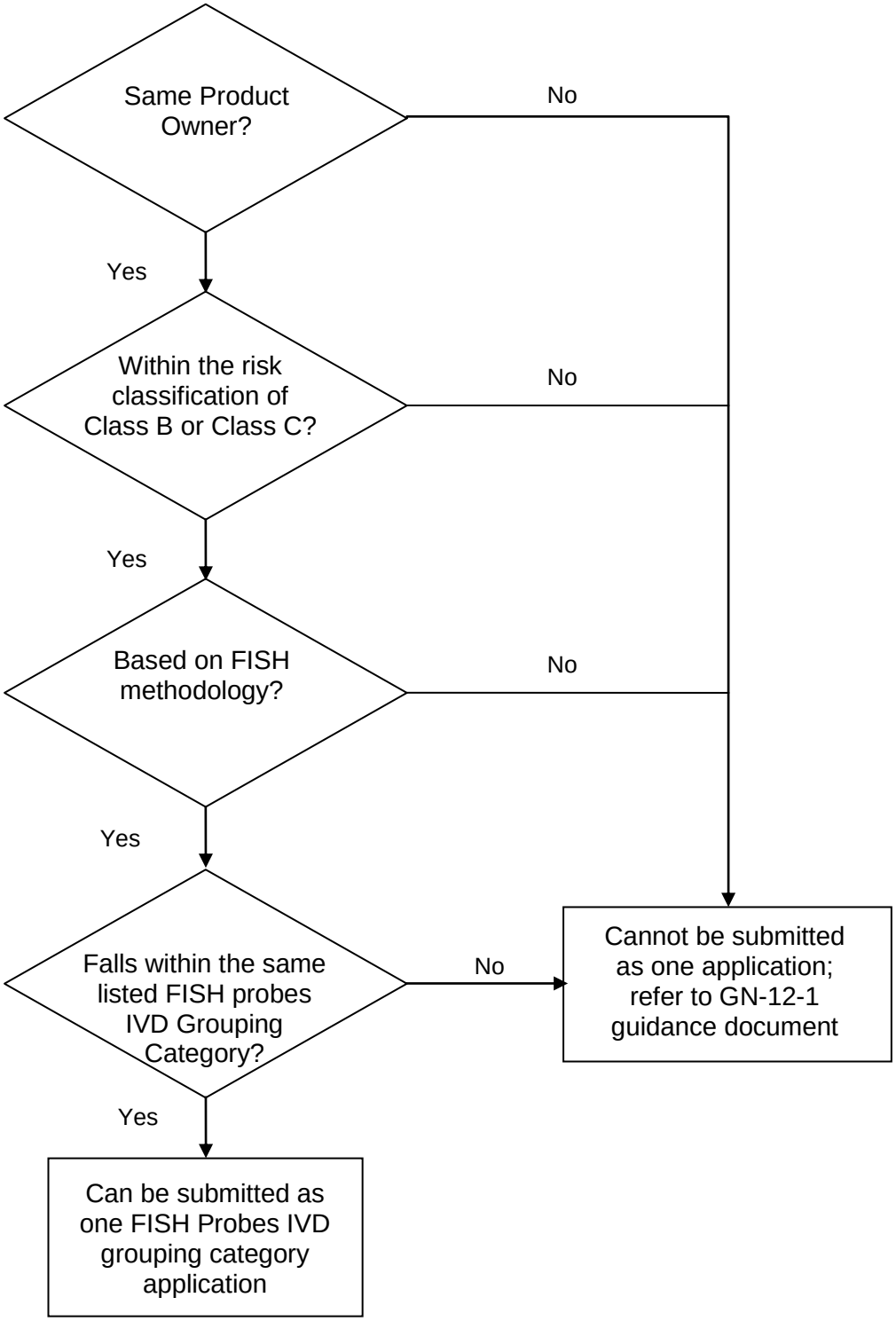
Information to support the intended purposes of all the reagents and their accessories must be submitted as part of the product registration application.

LIST OF FISH PROBES IVD GROUPING CATEGORIES

The list of FISH probes IVD grouping categories for the device specific grouping of Class B and Class C FISH probes IVD reagents and their accessories is a closed and positive list.

S/N	FISH Probes IVD Grouping Category (closed list)	Examples of Gene Targets (non-exhaustive list)
1	Selective Therapy	(i) ALK gene (ii) HER2
2	Pre-natal Testing	(i) Chromosomes 13, 21, 18, X and Y
3	Genetic Testing of Inheritable Disease	(i) ELN gene
4	Pathogen Identification	(i) Mycobacterium tuberculosis complex (MTC) (ii) Escherichia coli
5	Hematologic Disorder and Blood Cancer Markers	(i) Chromosomes 3, 7, 9 and 11
6	Other Cancer Markers	(i) LAMP2 gene (ii) Topoisomerase 2A gene

Decision Flowchart for Grouping of Class B and Class C FISH Probes IVD Grouping Category



Example:

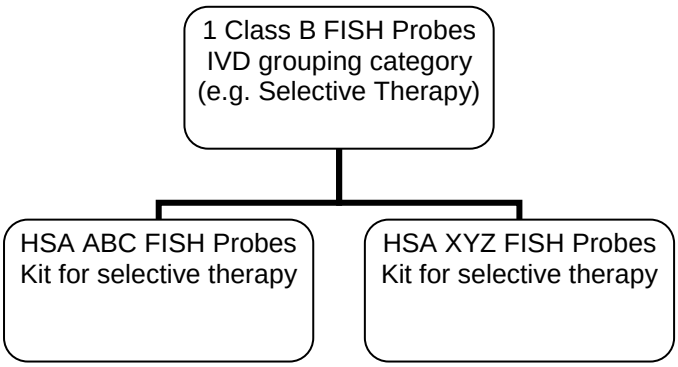


Figure 5 Example of a Class B FISH Probes IVD grouping category

Based on the example provided in Figure 5, the two FISH Probes IVD kits qualify for submission as one FISH Probes IVD grouping category and would result in two SMDR listings:

1. HSA ABC FISH Probes Kit (Selective Therapy)*
2. HSA XYZ FISH Probes Kit (Selective Therapy)**

* HSA ABC FISH Probes kit as one listing in which HSA is the product owner and ABC is the proprietary name.

** HSA XYZ FISH Probes kit as one listing in which HSA is the product owner and XYZ is the proprietary name.

Addition of New Models to a FISH Probes IVD Grouping Category Listing on the SMDR

The addition of new FISH Probes to an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new models being added fulfill the device specific grouping criteria (i.e. from the same product owner with the same proprietary name, of the same risk class and within the same FISH Probes IVD grouping category). Although, the new medical devices satisfy the device specific criteria to be grouped as a FISH Probes IVD grouping category with the registered devices, a new product registration application has to be submitted for the registration of these new devices. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

7. DEVICE SPECIFIC GROUPING OF IN VITRO FERTILISATION MEDIA

In vitro fertilization (IVF) is a procedure in which eggs (ova) from a woman's ovary are removed. They are fertilised with sperm in a laboratory procedure, and then the fertilised egg (embryo) is returned to the woman's uterus.

IVF is a medical procedure where an egg is fertilised by a sperm outside the body: *in vitro*. IVF instruments and media are necessary to ensure this medical procedure is performed successfully. IVF media products are used in a wide range of *in vitro* procedures, involving processing, manipulation and conditioning of sperm, oocytes, blastocysts and embryos. The intended use of IVF media may range from maintenance of the physiological homeostasis required to support and promote fertilisation *in vitro*, to the maintenance of the physiological homeostasis of the cells during the cryopreservation process and the minimisation of cellular damage during the freezing process. IVF media products may be comprised of a cocktail of physiological inorganic salts, energy sources, amino acids and proteins, and are available in a range of different formulations available.

A device specific grouping of IVF media grouping category comprises of a collection of IVF media that are:

- from the same product owner;
- compatible when used together and intended to be used for an IVF procedure category listed below

When IVF media products satisfy the criteria to be grouped into one of the four prescribed IVF media grouping categories, but have different device proprietary names, they may be grouped together during the product registration submission. However, the products may be listed separately on the SMDR based on their proprietary names on the IVF Media grouping categories, upon approval of the application. Alternatively, the product owner

and their applicants may decide choose to group these devices using the general grouping criteria in GN-12-1 guidance document.

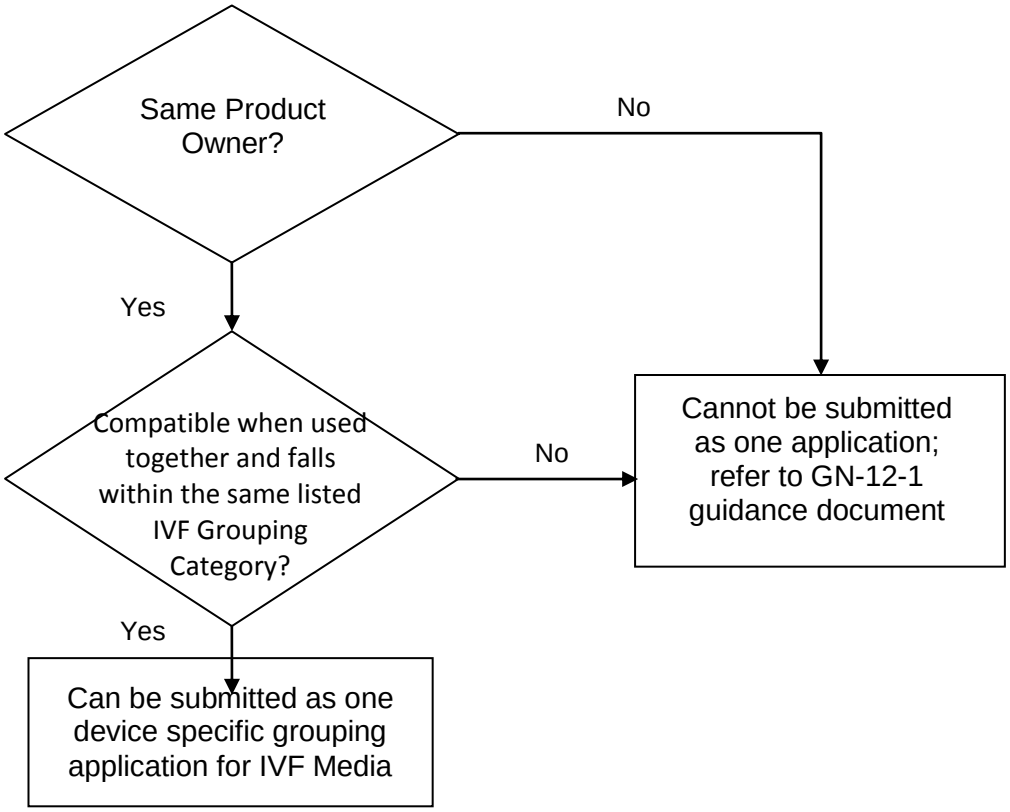
LIST OF IVF MEDIA GROUPING CATEGORIES

The list of IVF Media grouping categories is a closed and positive list.

S/N	IVF Media Grouping Category (closed list)	Examples of Media Types (non-exhaustive list)
1	IVF Media for Oocyte Handling	(i) Oocyte Obtaining (ii) Oocyte Processing (iii) Oocyte *In Vitro M*aturation (iv) Oocyte Polar Body Biopsy (v) Oocyte Cryopreservation (vi) Oocyte Storage (vii) Oocyte Thawing (viii) Oocyte Transport
2	IVF Media for Sperm Handling	(i) Semen/Sperm Obtaining (ii) Semen/Sperm Processing (e.g. gradient, swim up, immobilisation, washing) (iii) Semen/Sperm Cryopreservation (iv) Sperm Storage (v) Sperm Thawing (vi) Sperm Transport
3	IVF Media for Zygote Handling (processing/media for maintenance of zygotes/etc)	(i) IVF with Insemination (ii) IVF with Intracytoplasmic Sperm Injection (ICSI) (iii) Zygotes Maintenance (iv) Zygote Intrafallopian Transfer (ZIFT)

4	IVF Media for *In vitro* Embryo Handling	(i) *In Vitro* Embryo Obtaining (ii) *In Vitro* Embryo Culture And Assessment (iii) *In Vitro* Embryo Biopsy (iv) Assisted Hatching (v) *In Vitro* Embryo Cryopreservation (vi) *In Vitro* Embryo Storage (vii) *In Vitro* Embryo Thawing (viii) *In Vitro* Embryo Transport (ix) Embryo Transfer (Et)

Decision Flowchart for Grouping of IVF Media Products



Addition of New Models to an IVF Media Listing on the SMDR

The addition of new IVF media products an SMDR device listing through a CHANGE NOTIFICATION is only permissible if the new models being added fulfill the device specific grouping criteria and carry the same device proprietary name as the SMDR-listed medical devices. Although, the new medical devices satisfy the device specific criteria to be grouped as an IVF media grouping category with the registered devices, a new product registration application has to be submitted for the registration of these new devices. Kindly refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.