

# Unique Device Identification: Direct Marking of Devices

## Draft Guidance for Industry and Food and Drug Administration Staff

### DRAFT GUIDANCE

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U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
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## Preface

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# Unique Device Identification: Direct Marking of Devices

## Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

### I. Introduction

When finalized, this draft document will assist industry, particularly labelers, as defined under 21 CFR 801.3, and FDA staff in understanding FDA's requirements for direct marking of devices for unique device identification purposes. Under 21 CFR 801.45, "[a] device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use." This draft guidance defines some terms used in the Agency's regulations pertaining to the UDI direct marking requirements, including how FDA interprets the term "reprocessed" as used in 21 CFR 801.45. For additional background on the UDI system, see the UDI System Final Rule, published on September 24, 2013 (78 FR 58786) (the [UDI Rule](#)).

Throughout this draft guidance document, the terms "we," "us" and "our" refer to FDA staff from Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). "You" and "your" refers to the labeler, as that term is defined in 21 CFR 801.3.

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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131 **II. Background**

132 Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA),  
133 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and  
134 Innovation Act of 2012 (FDASIA), 126 Stat. 1061, amended the Federal Food, Drug, and  
135 Cosmetic Act to add Section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue  
136 regulations establishing a unique device identification system for medical devices along  
137 with implementation timeframes for certain medical devices. The UDI Rule, establishing  
138 the unique device identification system, was published on September 24, 2013 (78 FR  
139 58786) (the UDI Rule). It requires that the label and each device package of a medical  
140 device distributed in the United States bear a unique device identifier (UDI), unless an  
141 exception or alternative applies. The UDI regulations also require specified information  
142 to be submitted to FDA’s Global Unique Device Identification Database (GUDID). Most  
143 of the information submitted to GUDID is available to the public through [AccessGUDID](#).

144  
145 The UDI system seeks to improve the identification of medical devices by making it  
146 possible to rapidly and definitively identify a device and some key attributes that affect  
147 its safe and effective use. This will facilitate more accurate reporting of adverse events  
148 by making it easier to pinpoint the device at issue in the submitted report. FDA, health  
149 care providers, and industry may then more rapidly and precisely extract useful  
150 information from adverse event reports and thereby gain a better understanding of the  
151 underlying problems and improve the ability to take appropriate and better-focused  
152 corrective action.

153  
154 The UDI regulation at 21 CFR 801.45 requires a UDI direct marking on a device if the  
155 device is intended to be used more than once and intended to be reprocessed before each  
156 use. This requirement applies to class I, II and III devices, with certain exceptions. As  
157 explained in the preamble of the UDI Rule, direct marking requirements apply to devices  
158 that are intended to be used for months or years, sometimes many years. Because such  
159 devices are intended to be reprocessed and reused, they will inevitably be separated from  
160 their original labels and device packages. Direct marking helps to ensure the adequate  
161 identification of such devices through their distribution and use. However, the UDI Rule  
162 does not define “intended to be used more than once” or “reprocessed”. FDA’s  
163 interpretation of these terms as they are used in 21 CFR 801.45 is included in this  
164 document.

165 **III. Questions and Answers**

166 **A. Direct Marking**

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168 **1. What is direct marking?**

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170 Direct marking, for purposes of UDI requirements, is affixing a UDI permanently on the  
171 device itself.

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**2. Which devices are required to be directly marked?**

Under 21 CFR 801.45(a), if a UDI is required on a device label, that device is also required to have a UDI permanently affixed to the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. This requirement applies to all device classes, except class I devices that bear a Universal Product Code (UPC) on their label and device packages, as provided in 21 CFR 801.40(d). As explained in the preamble of the UDI Rule, direct marking requirements apply to devices that are intended to be used for months or years, sometimes many years. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. Direct marking best assures the adequate identification of such devices.

**3. What are the compliance dates for the direct marking requirements?**

The compliance date, i.e., the date by which you must comply with the UDI direct marking requirements, is based on the device category as shown below and also on the UDI webpage: [www.fda.gov/udi](http://www.fda.gov/udi). The compliance dates for UDI direct marking requirements are listed below:

<b>Direct Marking Compliance Date</b>	<b>Category of Device Intended to be Reused and Reprocessed</b>
9/24/2015	Life-sustaining and life-supporting devices, regardless of device class <sup>1</sup>
9/24/2016	Class III devices and devices licensed under the Public Health Service Act
9/24/2018	Class II devices
9/24/2020	Class I devices and unclassified devices

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**4. What about a device that has been manufactured and labeled prior to its UDI compliance date?**

Under 21 CFR 801.30(a)(1), a finished device manufactured and labeled prior to its compliance date for 21 CFR 801.20 is excepted from UDI labeling requirements until three years after the UDI compliance date for 21 CFR 801.20 for that particular device. Because direct marking requirements and data submission requirements are tied to the UDI labeling requirement at 21 CFR 801.20, the exception at 21 CFR 801.30(a)(1) applies to these requirements as well. For example, the compliance date for 21 CFR 801.20 for class III devices was September 24, 2014. Thus, an individual Class III device requiring direct marking that was manufactured and labeled on May 1, 2014, would not be required to be in

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<sup>1</sup>See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm>, UDI Resources for list.

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206 compliance with UDI labeling, direct marking, or GUDID data submission requirements  
207 until September 24, 2017.

208  
209 **5. Does FDA specify a method to directly mark a device?**  
210

211 No. We expect the permanent UDI to comply with the requirements of 21 CFR 801.45(b)  
212 and (c) and last throughout the expected use life of the device, taking into account expected  
213 usage and reprocessing. Possible methods to directly mark a device with a UDI include  
214 etching, attaching a permanent plaque to durable equipment, or affixing a permanent tag such  
215 as a radio frequency identification (RFID) tag to the device. However, we do not specify any  
216 particular approach to directly mark devices, because it would be difficult to account for the  
217 wide variety of existing devices, use conditions, and reprocessing methods for these devices.  
218 Moreover, technological advancements may lead to change in device usage, methods of  
219 device marking, and reprocessing procedures. The labeler should determine the appropriate  
220 method to provide such a marking on the device itself.  
221  
222

223 **6. For currently legally marketed devices, does affixing a permanent**  
224 **marking on the device to comply with UDI requirements require a**  
225 **premarket approval (PMA) supplement, a biologics license application**  
226 **(BLA) supplement, or a new premarket notification (510(k)) submission?**  
227

228 For devices classified through the de novo process or cleared in a 510(k) submission, we  
229 expect you to conduct analysis and/or testing to determine whether direct marking could  
230 significantly affect the safety or effectiveness of the device and to document the basis for  
231 your determination in the design history file. See 21 CFR 807.81(a)(3)(i). If any type of  
232 direct marking would interfere with the safety or effectiveness of your device, your device  
233 would qualify for the exception under 21 CFR 801.45(d)(1), and we encourage you to make  
234 use of this exception if it applies. If any type of direct marking would interfere with the  
235 safety or effectiveness of your device but you wish to directly mark your device, thereby not  
236 making use of this exception, clearance of a new 510(k) submission would generally be  
237 required, since we anticipate that a direct marking that would interfere with the safety or  
238 effectiveness of a device under 21 CFR 801.45(d)(1) also could significantly affect the safety  
239 or effectiveness of the device under 21 CFR 807.81(a)(3)(i). When in doubt, we encourage  
240 you to contact the CDRH or CBER review division relevant for your device to discuss your  
241 specific situation.  
242

243 For devices approved in a PMA or BLA, if adding a UDI direct marking would affect the  
244 safety or effectiveness of the device, this will require a supplemental PMA or BLA. 21  
245 CFR 814.39. FDA believes this will typically be the case. If, however, adding a UDI direct  
246 marking to a device approved in a PMA or BLA would not affect safety and effectiveness, no  
247 supplement would be required, but this change should be reported in an annual report. For  
248 PMA devices, please review the guidance, Modifications to Devices Subject to Premarket  
249 Approval (PMA) - The PMA Supplement Decision at  
250 <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm0>

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251 [89274.htm](http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm170166.pdf). For BLA devices, please review the guidance, Changes to an Approved  
252 Application: Biological Products at  
253 [http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinform](http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm170166.pdf)  
254 [ation/guidances/blood/ucm170166.pdf](http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm170166.pdf) .  
255  
256

257 **7. If a PMA supplement, BLA supplement, or new 510(k) is required**  
258 **as a result of UDI direct marking requirements, are user fees also**  
259 **required?**  
260

261 Yes. You must pay the applicable user fee, if any, if you submit a PMA supplement, a BLA  
262 supplement or a new 510(k) submission. There are no user fee waivers for submitting a  
263 PMA supplement, a BLA supplement, or a new 510(k) submission as a result of UDI direct  
264 marking requirements. However, FDA encourages you to bundle your required submissions  
265 rather than submit individually, which will reduce both administrative and user fee burdens.  
266 See FDA guidance entitled “Bundling Multiple Devices or Multiple Indications in a Single  
267 Submission” issued on June 22, 2007 ([Bundling Guidance](#)).  
268  
269

270 **8. What are the GUDID data submission requirements for devices**  
271 **that must be directly marked with a UDI?**  
272

273 Under 21 CFR 801.40(b), each UDI must include a device identifier (DI) segment. The UDI  
274 on the device’s label may be the same or different from the UDI directly marked on the  
275 device (see section III.B.2), which means two different DIs may be associated with the same  
276 device at the base package level. For the purposes of this draft guidance, the DI on a device’s  
277 label is referred to as the primary DI, and the DI that is directly marked on a device is  
278 referred to as the direct-mark DI (DM-DI).  
279

280 The UDI regulation at 21 CFR 830.310 sets forth the information submission requirements  
281 for all devices required to bear a UDI on their label. Each primary DI must be submitted to  
282 GUDID, as required by 21 CFR 830.310(b)(1). If the DI and the DM-DI are the same, no  
283 additional information needs to be submitted to GUDID. If the DI and the DM-DI are  
284 different, the labeler must submit the DM-DI. 21 CFR 830.310(b)(3). In this case, the  
285 labeler should check the box “DM DI Different from Primary DI” and enter the DM-DI  
286 Number as part of its GUDID submission. As stated in section III.A.9., we expect the  
287 records required under 21 CFR 830.360 to indicate whether DM-DI is the same or different  
288 from the primary DI.  
289

290 If you are applying one of the exceptions listed in 21 CFR 801.45(d), you should check the  
291 box “Device Subject to Direct Marking (DM), but Exempt.” We outline the general  
292 exceptions to the UDI direct marking requirements in section III.D of this draft guidance.  
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**9. What are the recordkeeping requirements for devices that must be directly marked with a UDI?**

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The record requirements under 21 CFR 830.360 apply to UDI direct markings as well as UDIs placed on the device label and device packages. We expect that the records will indicate whether a device is directly marked and whether the DM-DI is the same or different from the primary DI. The records do not need to list each individual UDI [DI plus production identifier (PI)] separately. Rather, the labeler should maintain records for each DI with its associated range of PIs. The records should be regularly updated to reflect additional PIs associated with each DI. If your device falls within one of the exceptions from direct marking under 21 CFR 801.45(d) and you decide to make use of such, you are required to keep records supporting this decision in the design history file (see 21 CFR 801.45(e)). If you determine any type of direct marking would interfere with the safety and effectiveness of the device (21 CFR 801.45(d)(1)), we expect the rationale that supports your decision to be scientifically justified by analysis and/or testing. If the device cannot be directly marked because it is not technologically feasible (21 CFR 801.45(d)(2)), we expect you to document the rationale for the technological infeasibility in the design history file.

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**10. May a labeler voluntarily comply with direct marking requirements?**

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Yes. We encourage affixing a UDI permanently on devices even when not required. If a labeler of a device that is not required to bear a UDI under 21 CFR 801.45 directly marks such a device voluntarily, or before the compliance date of UDI direct marking requirements, GUDID data submission requirements applicable to UDI direct marking would also be voluntary. Please see sections III.A.6. and 7. above regarding potential impact on safety and effectiveness and the potential requirement for an additional premarket submission in conjunction with applying a UDI direct marking to a currently marketed device.

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**B. UDI Format**

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**1. Is the full UDI required to be directly marked on the device?**

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Yes. A UDI direct marking must be either identical to the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from any device package containing the device (21 CFR 801.45(b)). Either way, unless excepted, the full UDI must be directly marked, including the device identifier (DI) and any required production identifiers (PI). See 21 CFR 801.40(b) and 801.45. Note that production identifiers are not required in UDIs of class I devices. 21 CFR 801.30(d). Also note that class I devices that bear a Universal Product Code (UPC) on their label and device packages are not required to comply with UDI direct marking requirements. See 21 CFR 801.40(d).

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336 **2. Does the UDI directly marked on the device need to be identical to**  
337 **the UDI on the device label?**  
338

339 No. Under 21 CR 801.45(b), the labeler may choose to directly mark the device with a UDI  
340 identical to the UDI that appears on the label of the device, or with a different UDI to  
341 distinguish the unpackaged device from any device package containing the device.  
342

343 **3. For a UDI direct marking, are both the plain text and AIDC forms**  
344 **required?**  
345

346 No. Unlike the UDI on labels and packages, under 21 CFR 801.45(c), when a device must  
347 bear a UDI direct marking, the UDI may be provided through either or both of the following:  
348 (1) easily readable plain-text or (2) automatic identification and data capture (AIDC)  
349 technology or any alternative technology that will provide the UDI of the device on demand.  
350 Both the plain text and the AIDC forms of the directly marked UDI should adhere to the UDI  
351 format specified by the FDA-Accredited Issuing Agency. See 21 CFR 830.20 and “UDI  
352 Formats by FDA-Accredited Issuing Agency (May 7, 2014)” ([UDI Formats](#)).  
353

354 **4. If the UDI that appears on the device label changes, must the**  
355 **directly marked UDI be replaced?**  
356

357 No. Under 21 CFR 801.45(d)(4), once a device has been marked in compliance with the  
358 UDI direct marking requirements, there is no requirement to replace the UDI direct marking  
359 even if the UDI that appears on the label changes.

360 **C. Reprocessing**

361 **1. How is “intended to be used more than once” defined?**  
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363

364 For the purposes of the UDI direct marking requirements, under 21 CFR 801.45, "intended to  
365 be used more than once" means intended for repeated uses on or by different patients, for  
366 example, where a device is cleared or approved and labeled for repeated uses on or by  
367 different patients.  
368

369 **2. What does FDA consider “reprocessed” for the purpose of direct**  
370 **marking?**  
371

372 Reprocessing is defined as validated processes used to render a medical device, which has  
373 been previously used or contaminated, fit for a subsequent use. See “Reprocessing Medical  
374 Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry  
375 and Food and Drug Administration Staff” issued on March 17, 2015 ([Reprocessing](#)  
376 [Guidance](#)). Reprocessing is generally intended to remove blood, tissue, biological debris,  
377 and other contaminants and to inactivate infectious microbes so that devices are safe for the  
378 next patient.

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380 For purposes of UDI direct marking requirements, we consider a device that is intended to be  
381 cleaned and either sterilized or disinfected before each use to be intended to be reprocessed.  
382 If a device is intended only to be cleaned between uses by different patients, this would not  
383 be considered reprocessing for the purposes of the UDI direct marking requirements. If the  
384 device is intended to be used more than once on or by the same patient, and not on or by  
385 different patients, the device does not need to be directly marked with a UDI.

386

**D. Exceptions to Direct Marking**

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**1. What exceptions are there to the UDI direct marking requirements?**

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391 There are four direct marking exceptions outlined in 21 CFR 801.45(d). The requirement of  
392 21 CFR 801.45(a) does not apply to any device that meets any of the following criteria:

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1. Any type of direct marking would interfere with the safety or effectiveness of the device;
2. The device cannot be directly marked because it is not technologically feasible;
3. The device is a single use device and is subjected to additional processing and manufacturing for the purpose of an additional single use; or
4. The device has been previously marked under 21 CFR 801.45(a).

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A “single use device” means a device that is intended for one use, or on a single patient during a single procedure. 21 U.S.C. 321(l). We interpret 21 CFR 801.45(d)(3) to mean that the UDI direct marking requirements do not apply to a device that the original labeler (as defined in 21 CFR 801.3) intends for one use, or use on a single patient during a single procedure, even if, subsequent to its initial use, the device is subjected to additional processing and manufacturing for the purpose of an additional single use on another patient. However, such reuse of a single use device would generally require additional clearance or approval unless 510(k)-exempt,<sup>2</sup> as well as compliance with general UDI labeling and data submission requirements by the entity performing the additional processing and manufacturing for the purpose of an additional single use. In contrast, for purposes of UDI direct marking requirements under 21 CFR 801.45, a device intended for repeated use on or by different patients is “intended to be used more than once” and is thus subject to UDI direct marking requirements (see section III.C.1).

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<sup>2</sup> See 21 U.S.C. 360(o) and “Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm>) regarding 510(k) submissions for reprocessed single-use devices.

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415 Please note that a reprocessed and/or relabeled single use device must comply with the  
416 general UDI labeling and data submission requirements. See definition of “labeler” under 21  
417 CFR 801.3 and requirements for when a device is relabeled under 21 CFR 830.60.

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419

**2. Does a non-UDI direct marking (such as the name of the company or part or catalog number) on a device itself meet the UDI direct marking requirements?**

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421

422

423 No. The name of the company or part/catalog number only does not meet the UDI direct  
424 marking requirements under 21 CFR 801.45. If your device design with a non-UDI direct  
425 marking has been cleared or approved, we are unlikely to find merit in a justification for an  
426 exception under 21 CFR 801.45(d)(1) that direct marking would interfere with the safety or  
427 effectiveness of the device. In addition, lack of space because non-UDI direct marking has  
428 taken up the otherwise available space for a UDI direct marking will typically not be  
429 sufficient justification for an exception under 21 CFR 801.45(d)(2) that the device cannot be  
430 directly marked because it is not technologically feasible.

431

432

**3. What is the process for making use of a 21 CFR 801.45(d) exception from a direct marking requirement?**

433

434

435 As discussed in III.A.9., under 21 CFR 801.45(e), a labeler who decides that an exception  
436 under 21 CFR 801.45(d) applies to its device must document the basis of that decision in the  
437 design history file required by 21 CFR 820.30(j). As explained in III.A.8., in your GUDID  
438 submission, you should check the box “Device Subject to Direct Marking (DM), but  
439 Exempt.”

440

441

**4. What is the process for requesting a specific alternative to direct marking? How do I request an exception from or alternative to the direct marking requirements?**

442

443

444

445 The UDI regulation at 21 CFR 801.55 outlines the process for requesting a specific  
446 alternative to any UDI requirement, including direct marking, by submitting a request to  
447 FDA. Under 21 CFR 801.55(c), FDA may grant an alternative to UDI direct marking or any  
448 other UDI labeling requirement, if we determine that:

449

(a) An alternative would provide for more accurate, precise, or rapid device  
450 identification; or

450

451

(b) An alternative would better ensure the safety or effectiveness of the device.

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Please note that there is no reason to submit a 21 CFR 801.55 request for exception from  
UDI direct marking requirements if any exception under 21 CFR 801.45(d) is applicable.  
Requests for the current instructions on requesting an alternative may be submitted using the  
online form by clicking the FDA UDI Help Desk link at [www.fda.gov/udi](http://www.fda.gov/udi).