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Section III: Guidance Documents

**Appeals**
- Center for Devices and Radiological Health Appeals Processes (May 2013) (New)
- Center for Devices and Radiological Health Appeals Processes: Questions and Answers About 517A (July 2014) (New)

**Clinical Studies and Research**
- Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects (March 1999)
- Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials (February 2010)
- IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed (August 2013) (New)
- Design Considerations for Pivotal Clinical Investigations for Medical Devices (November 2013) (New)
- Reporting of Computational Modeling Studies in Medical Device Submissions (January 2014) (New)
- FDA Decisions for Investigational Device Exemption Clinical Investigations (August 2014) (New)
- Evaluation of Sex-Specific Data in Medical Device Clinical Studies (August 2014) (New)

**Combination Products**
- Classification of Products as Drugs and Devices and Additional Product Classification Issues (June 2011)
- Current Good Manufacturing Practice Requirements for Combination Products (January 2015) (New)

**Consensus Standards**
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition (September 2007)
- Recognition and Use of Consensus Standards (September 2007)
- Frequently Asked Questions on Recognition of Consensus Standards (September 2007)
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (May 2014) (New)

**Design and Development**
- Design Control Guidance for Medical Device Manufacturers (March 1997)
- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (July 2007)
- Applying Human Factors and Usability Engineering to Optimize Medical Device Design (June 2011)
• Medical Device Development Tools (November 2013) (New)
• Design Considerations for Devices Intended for Home Use (November 2014) (New)

**Diagnostics and LDTs**
• Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests (March 2007)
• Pharmacogenetic Tests and Genetic Tests for Heritable Markers (June 2007)
• In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions (June 2010)
• Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions (November 2013)
• Administrative Procedures for CLIA Categorization (March 2014) (New)
• In Vitro Companion Diagnostic Devices (August 2014) (New)
• FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs) (October 2014) (New)
• Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs) (October 2014) (New)
• Molecular Diagnostic Instruments with Combined Functions (November 2014) (New)

**Electronics and Software**
• General Principles of Software Validation (January 2002)
• Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 2005)
• Acceptable Media for Electronic Product User Manuals (March 2010)
• Radio Frequency Wireless Technology in Medical Devices (August 2013) (New)
• Mobile Medical Applications (February 2014) (New)
• Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014) (New)
• Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (February 2015) (New)

**Exemption**
• Guidance on IDE Policies and Procedures (January 1998)
• Procedures for Class II Device Exemptions from Premarket Notification (February 1998)
• Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies (October 2013) (New)
• Humanitarian Device Exemption (HDE): Questions and Answers (March 2014) (New)
• Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements (August 2014) (New)
• Custom Device Exemption (September 2014) (New)

Fees
• Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products (February 2003)
• Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA (November 2004)
• User Fees for 513(g) Requests for Information (April 2012)
• User Fees and Refunds for Premarket Notification Submissions (510(k)s) (April 2013)
• User Fees and Refunds for Premarket Approval Applications and Device Biologics License Applications (April 2013)
• FY 2015 Medical Device User Fee Small Business Qualification and Certification (August 2014) (New)

Inspections
• Guide to Inspection of Quality Systems (August 1999)
• Implementation of Third Party Programs Under the FDA Modernization Act of 1997 (February 2001)
• Manufacturer’s Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007 (March 2009)
• Inspection by Accredited Persons Under the Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007; Accreditation Criteria (August 2009)
• Inspection of Medical Device Manufacturers (February 2011)
• Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I (February 2013)

Labeling
• Labeling: Regulatory Requirements for Medical Devices (August 1989)
• Human Factors Principles for Medical Device Labeling (September 1993)
• Alternative to Certain Prescription Device Labeling Requirements (January 2000)
• Guidance on Medical Device Patient Labeling (April 2001)
• Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals (July 2001)
• Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (November 2004)
• Addition of URLs to Electronic Product Labeling (September 2010)
• Internet/Social Media Platforms with Character Space Limitations — Presenting Risk and Benefit
Information for Prescription Drugs and Medical Devices (June 2014) (New)

- Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014) (New)
- Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex (December 2014) (New)

**Postmarket Surveillance**

- Procedures for Handling Section 522 Postmarket Surveillance Studies (August 2011)

**Premarket Submissions**

- Quality System Information for Certain Premarket Application Reviews (February 2003)
- Providing Regulatory Submissions in Electronic Format (October 2003)
- Third-Party Review of Premarket Notifications (September 2004)
- Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)
- Bundling Multiple Devices or Multiple Indications in a Single Submission (June 2007)
- Pediatric Information for X-ray Imaging Device Premarket Notifications (May 2012)
- Humanitarian Use Device (HUD) Designations (January 2013)
- Priority Review of Premarket Submissions for Devices (May 2013)
- The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions and Answers (August 2013) (New)
- eCopy Program for Medical Device Submissions (October 2013) (New)
- Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff (February 2014) (New)
- Premarket Assessment of Pediatric Medical Devices (March 2014) (New)
- Types of Communication During the Review of Medical Device Submissions (April 2014) (New)
- Providing Information about Pediatric Uses of Medical Devices (May 2014) (New)

**Premarket Submissions – 510(k)s**

- Preparation of Premarket Notification [510(k)] Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems (July 1995)
- Deciding When to Submit a 510(k) for a Change to an Existing Device (January 1997)
- The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications (March 1998)
- Determination of Intended Use for 510(k) Devices (December 2002)
- Format for Traditional and Abbreviated 510(k)s (August 2005)
• Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions [510(k)s] for Reprocessed Single-Use Medical Devices (September 2006)
• FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals (October 2012)
• Refuse to Accept Policy for 510(k)s (December 2012)
• The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications (July 2014) (New)
• Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics (July 2014) (New)
• Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers (December 2014) (New)

Premarket Submissions – de Novo
• New Section 513(f)(2) – Evaluation of Automatic Class III Designation (February 1998)
• Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications (March 2012)
• De Novo Classification Process (Evaluation of Automatic Class III Designation) (August 2014)

Premarket Submissions - PMAs
• Premarket Approval Application Modular Review (November 2003)
• Real-Time Premarket Approval Application (PMA) Supplements (April 2006)
• The Review and Inspection of Premarket Approval Application Manufacturing Information and Operations (January 2008)
• Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process (December 2008)
• 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes (April 2011)
• FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals (October 2012)
• Acceptance and Filing Reviews for Premarket Approval Applications (December 2013)
• Annual Reports for Approved Premarket Approval Applications (February 2014)
• Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval (April 2014) (New)

Registration and Classification
• Premendment Status (February 1997)
• Assayed and Unassayed Quality Control Material (June 2007)
• FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act (April 2012)
• Medical Device Classification Product Codes (April 2013)
• Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) (January 2014) (New)
• Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types (January 2015) (New)
• General Wellness: Policy for Low Risk Devices (January 2015) (New)

Reporting and Tracking
• Medical Device Reporting for User Facilities (April 1996)
• Medical Device Reporting – Alternative Summary Reporting (ASR) Program (October 2000)
• Medical Device Reporting – Remedial Action Exemption (September 2001)
• Procedures for Handling Post-Approval Studies Imposed by PMA Order (June 2009)
• Medical Device Reporting for Manufacturers (May 2013) (New)
• Questions and Answers about eMDR - Electronic Medical Device Reporting (February 2014) (New)
• Medical Device Tracking (March 2014) (New)
• Distinguishing Medical Device Recalls from Medical Device Enhancements (October 2014) (New)

Single-Use Devices
• Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (August 2000)
• Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors (July 2001)
• Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors: Three Additional Questions (July 2002)
• Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (May 2006)
• Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 2015) (New)

Unique Device Identifier (UDI)
• Unique Device Identification System Final Rule (September 2013) (New)
• Global Unique Device Identification Database (GUDID) (June 2014) (New)
• Unique Device Identification System: Small Entity Compliance Guide (August 2014) (New)