TABLE OF CONTENTS

Introduction

Section I: Overview

• FDA Medical Device Regulation System3

- Guidance for Device Manufacturers......31

Section II: Code of Federal Regulations

- Part 800 General
- Part 801 Labeling
- Part 803 Medical Device Reporting
- Part 806 Reports of Corrections and Removals
- Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- Part 808 Exemptions from Federal Preemption of State and Local Medical Device Requirements
- Part 809 In Vitro Diagnostic Products for Human Use
- Part 810 Medical Device Recall Authority
- Part 812 Investigational Device Exemptions
- Part 814 Premarket Approval of Medical Devices
- Part 820 Quality System Regulation
- Part 821 Medical Device Tracking Requirements
- Part 822 Postmarket Surveillance
- Part 860 Medical Device Classification Procedures

Section III: Guidance Documents

- Part 861 Procedures for Performance Standards Development
- Part 895 Banned Devices
- List of Regulated Medical Devices, Part 862-892

Registration and Classification

- New Section 513(f)(2) Evaluation of Automatic Class III Designation
- The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications
- The Least Burdensome Provisions of the FDA Modernization Act: Concept and Principles
- Establishment of Medical Device Registration
- FDA and Industry Procedures for 513(g) Requests for Information

Design and Development

- Design Control Guidance for Medical Device Manufacturers
- Use of Bayesian Statistics in Medical Device Clinical Trials

Premarket Submissions

- Preparation of Premarket Notification 510(k) Applications for Communications Systems (Powered and Non-Powered) and Powered Environmental Control Systems
- Deciding When to Submit a 510(k) for a Change to an Existing Device
- Bundling Multiple Devices or Multiple Indications in a Single Submission

- Determination of Intended Use of 510(k) Devices
- Quality System Information for Certain Premarket Application Reviews
- Premarket Approval Application Filing Review
- Premarket Approval Application Modular Review
- Premarket Assessment of Pediatric Devices
- FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment
- Content of Premarket Submissions for Software Contained in Medical Devices
- Format for Traditional and Abbreviated 510(k)s
- Real-Time Premarket Approval (PMA) Application Supplements
- MDUFMA, Validation Data in Premarket Notification Submissions (510(k)s for Reprocessed, Single-Use Medical Devices
- Annual Reports for Approved Premarket Approval Applications (PMA)
- Interactive Review for Medical Device Submissions
- Expedited Review of Premarket Submissions for Devices

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
- User Fees and Refunds for Premarket Approval Applications

- Resolution of Disputes Concerning Payment or Refund of Medical Device User Fees Under MDUFMA
- User Fees and Refunds for Premarket Notification Submissions
- User Fees for 513(g) Requests for Classification
- Medical Device User Fee Small Business Qualification and Certification

Exemption

- Center for Devices and Radiological Health's Investigational Device Exemption (IDE) Refuse to Accept Policy
- Guidance on IDE Policies and Procedures
- Exemptions from Premarket Notification and Reserved Devices, Class I
- Procedures for Class II Device Exemptions from Premarket Notification
- Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff: Humanitarian Device Exemption (HDE) Regulations: Questions and Answers

Inspection

- Guide to Inspections of Quality Systems
- Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program
- Accredited Persons Inspection Program
- Inspection of Medical Device Manufacturers
- Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act; Accreditation Criteria

- Manufacturer's Notification of the Intent to Use an Accredited Person under the Accredited Persons Inspection Program
- Guide to Inspections of Foreign Medical Device Manufacturers

Reporting and Tracking

- Medical Device Reporting for User Facilities
- Medical Device Reporting for Manufacturers
- Medical Device Reporting: Alternative Summary Reporting (ASR) Program
- Medical Device Recalls and Corrections and Removals Information from the FDA
- EMDR Electronic Medical Device Reporting
- Medical Device Tracking
- Unique Device Identification (UDI) System for Medical Devices

Safety

 Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management

Software

- General Principles of Software Validation
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software

Single-Use Devices

- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals
- Frequently-Asked-Questions about the Reprocessing and Reuse of Single-Use Devices by Third-Party and Hospital Reprocessors

- Reprocessing of Single-Use Devices; Frequently Asked Questions – Three Additional Questions
- Compliance with Section 301 of MDUFMA, as Amended - Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices

Labeling

- Labeling Regulatory Requirements for Medical Devices
- Human Factors Principles for Medical Device Labeling
- Guidance on Labeling for Laboratory Tests
- Alternative to Certain Prescription Device Labeling Requirements
- Medical Device Patient Labeling
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
- Consumer-Directed Broadcast Advertising of Restricted Devices
- Automatic Identification of Medical Devices
- Addition of URLs to Electronic Product Labeling