TABLE OF CONTENTS

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

Section III: Guidance Documents

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

- 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

- 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