

|   |   |  |
|---|---|--|
| SUBJECT:<br><br>MEDICAL DEVICE PMA PREAPPROVAL AND PMA POSTMARKET INSPECTIONS |   | IMPLEMENTATION DATE<br><br>March 5, 2012 |
|   |   | COMPLETION DATE<br><br>March 5, 2016     |
| DATA REPORTING  |   |  |
| PRODUCT CODES   | PRODUCT/ASSIGNMENT CODES  |  |
| 73-91   | 83001    Premarket Approval Inspections<br>83001A    Postmarket Inspections |  |
|   |   |  |

**Index for Compliance Program 7383.001**

**Coversheet**

**Field Reporting Requirements**

**Part I**

**Background**

- A. Premarket Approval and the Quality System Regulation
- B. The Medical Device Reporting Regulation
- C. The Medical Device Tracking Regulation
- D. The Corrections and Removal Regulation
- E. The Registration and Listing Regulation

**Part II**

**Implementation**

- A. Objectives
  - 1. PMA Preapproval Inspections
  - 2. PMA Postmarket Inspections
- B. Program Management Instructions
  - 1. PMA Preapproval Inspections
  - 2. PMA Postmarket Inspections

**Part III**

**Inspectional**

- A. Operations
  - 1. Inspectional Strategy
  - 2. Inspectional Instructions
- B. Program Management Instructions
  - 1. Special Instructions Concerning Process Validation
  - 2. Special Instructions Concerning Design Controls
  - 3. Special Instructions for Sterilization Processes
- C. Reporting

**Part IV**

**Analytical**

**Part V**

**Regulatory/Administrative Follow-up**

- A. PMA Preapproval Inspections
  - 1. Compliance Decisions
- B. PMA Postmarket Inspections
  - 1. Quality System/GMP Regulatory/Administrative Follow-up
  - 2. MDR Regulatory/Administrative Follow-up
  - 3. Tracking Regulatory/Administrative Follow-up
  - 4. Corrections and Removals Regulatory/Administrative Follow-up
  - 5. Registration and Listing Regulatory/Administrative Follow-up

**Part VI**

**References and Program Contacts**

**Attachments:**

**Attachment A**

**Attachment B**

**Attachment C**

Notification of PMA Postmarket Inspection Form

CDRH Office of Compliance Organizational Chart

CDRH Office of In Vitro Diagnostic Devices Organizational Chart