Overview of Medical Device Reporting

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U.S. Food and Drug Administration
Value of Medical Device Reports

Consumers and Industry:
• Understand device safety and performance
• Design improvement

FDA:
• Monitor device safety and performance
• Assess need for regulatory action
Learning Objectives

• Describe FDA’s regulatory authority for medical device reporting
• Define “MDR reportable event”
• Identify who reports to FDA and how
• Explain how FDA uses Medical Device Reports (MDRs)
• Demonstrate how to search for MDRs
FDA’s Regulatory Authority
Regulatory Authority

• Section 519 of the Food, Drug, and Cosmetic Act
  – Pertains to records and reports on medical devices
  – Grants FDA authority to require mandatory medical device reports from
    • Manufacturers
    • Importers
    • Device User Facilities
Medical Device Reporting Regulation

• Title 21 of Code of Federal Regulations (CFR), Part 803
• Establishes regulatory pathway for collecting reportable adverse event data
• Defines critical reporting roles, responsibilities, and deadlines
“MDR Reportable Event”
MDR Reportable Event

An MDR reportable event reasonably suggests a marketed device:

• May have caused or contributed to a death or serious injury,

21 CFR 803.3(o)
MDR Reportable Event

An MDR reportable event reasonably suggests a marketed device:

• Malfunctioned, and

• Likely to cause or contribute to death or serious injury were it to recur

21 CFR 803.3(o)
Who Reports MDRs and How

Mandatory Reporters
Voluntary Reporters
Mandatory Reporters

- Manufacturers
  - 21 CFR 803.3(l)

- Importers
  - 21 CFR 803.3(j)

- Device User Facilities
  - Example: Hospitals and Nursing Homes
  - 21 CFR 803.3(d)
How to Report: Mandatory Reporters

Manufacturers and Importers:

- Electronic submission **only**
- Electronic Medical Device Reporting (eMDR) Final Rule effective August 14, 2015
- Use Electronic Submissions Gateway (ESG)
  - eMDR Guidance
How to Report: Mandatory Reporters

User Facilities:

• Electronic submission encouraged
• eMDR Final Rule permits written reports
  – Use Form 3500A
• Guidance: Medical Device Reporting For User Facilities
Who Reports MDRs and How

Voluntary Reporters
Voluntary Reporters

- Patients
- Health care Professionals
- Caregivers
How to Report: Voluntary Reporters

• Online through MedWatch
• By postal mail
  – Voluntary Reports – Form 3500
  – Consumer-friendly version – Form 3500B
How FDA Uses Medical Device Reports
Information Analysis

- CDRH values adverse event data collection and management
- Maintains adverse event database and data files
- Provides eMDR support for mandatory reporters
Medical Device Reports

• Over 800,000 reports received per year

• Reviewed by MDR analysts
  – Medical and technical professionals
    o Nurses
    o Engineers
    o Scientists
MDRs Used to: Identify Trends

- Common or Novel
- Frequency of reported event
- Severity of the event
- Associated risks
MDRs Used to: Identify Possible Actions

• FDA inspection of manufacturer
• Changes to device labeling
• Notices to the public
  – Example: Safety Communications
• Device recall
Searching for Medical Device Reports
MAUDE

- Manufacturer and User Facility Device Experience (MAUDE)
- Publicly searchable database of adverse event reports
  - User facility reports since 1991
  - Voluntary reports since 1993
  - Manufacturer reports since August 1996
MAUDE

- Allows you to search using a variety of criteria
- Limit of 500 results per search
MAUDE

• Important notes:
  – Reports are redacted
  – “Download Files” feature best for data more than 10 years old
Example Search
Example Search

Product Code Classification Database
## Example Search

500 records meeting your search criteria returned. The results are incomplete - please narrow your search.

<table>
<thead>
<tr>
<th>Manufacturer</th>
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<th>Date Report Received</th>
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**Model Number** 70-1154-IMP0012  
**Device Problem** Failure to Osseointegrate  
**Event Type** Malfunction  
**Event Description**  
It was reported that a hahn tapered implant failed. Multiple attempts were made to obtain additional information from the customer. However, no additional information was provided.

**Manufacturer Narrative**  
Multiple attempts were made to obtain the information from the customer, but no information was provided. A follow-up report will be submitted if new information is received from the customer, and/or when the investigation is completed.

**Search Alerts/Recalls**
Summary

• MDRs are critical to public health

• Reports help generate postmarket data

• Information used to monitor medical device performance and safety

• Reported adverse event information is publicly available
Contact Information

Interpretations of MDR policy: MDR Policy Group

- Phone: (301) 796-6670 (voice)
- Email: MDRPolicy@fda.hhs.gov
Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 125 modules
   - Videos, audio recordings, power point presentations, software-based “how to” modules
   - Mobile-friendly: access CDRH Learn on your portable devices
   - [www.fda.gov/CDRHLearn](http://www.fda.gov/CDRHLearn)

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics
   - [www.fda.gov/DeviceAdvice](http://www.fda.gov/DeviceAdvice)

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: [www.fda.gov/DICE](http://www.fda.gov/DICE)
Your Call to Action

• Understand your reporting responsibilities
• Notify FDA of reportable events
• Use the MAUDE database and educational resources