Overview of Medical Device Reporting

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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
    - Nurses
    - Engineers
    - Scientists

MDRs Used to: Identify Trends

- Common or Novel
- Frequency of reported event
- Severity of the event
- Associated risks

Limitations of Data

MDRs Used to: Identify Possible Actions

- FDA inspection of manufacturer
- Changes to device labeling
- Notices to the public
  - Example: Safety Communications
- Device recall

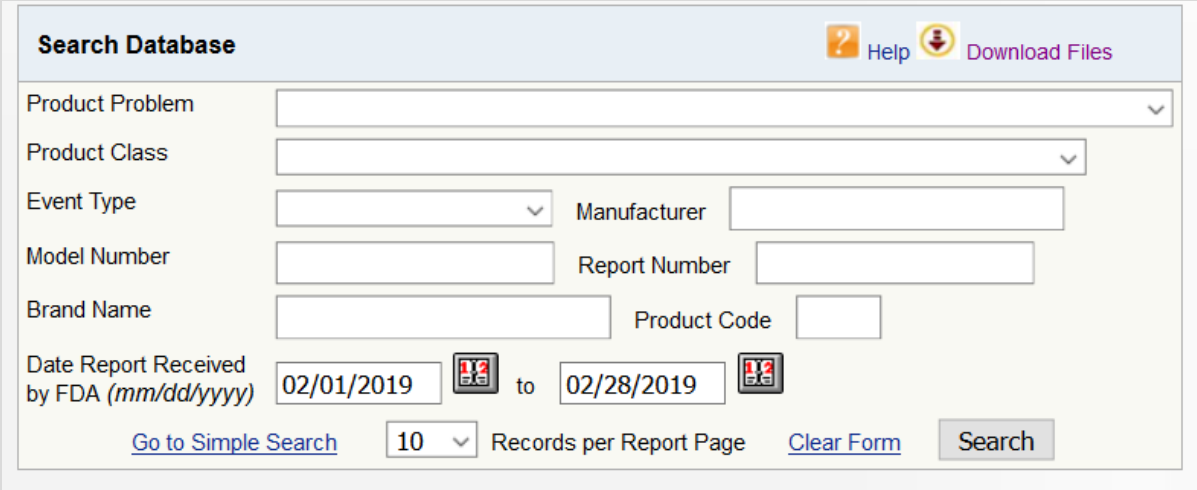
Searching for Medical Device Reports

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

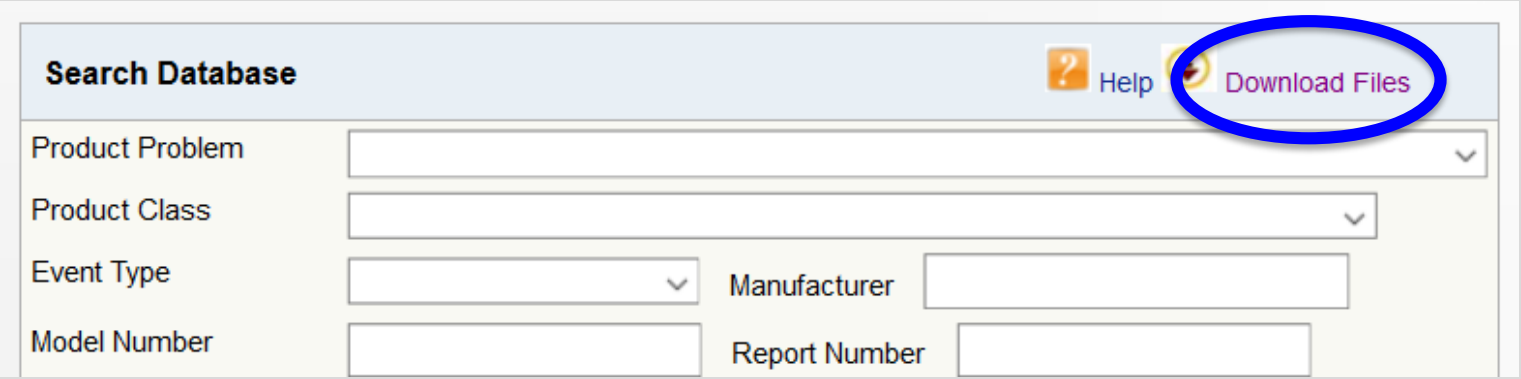
MAUDE

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

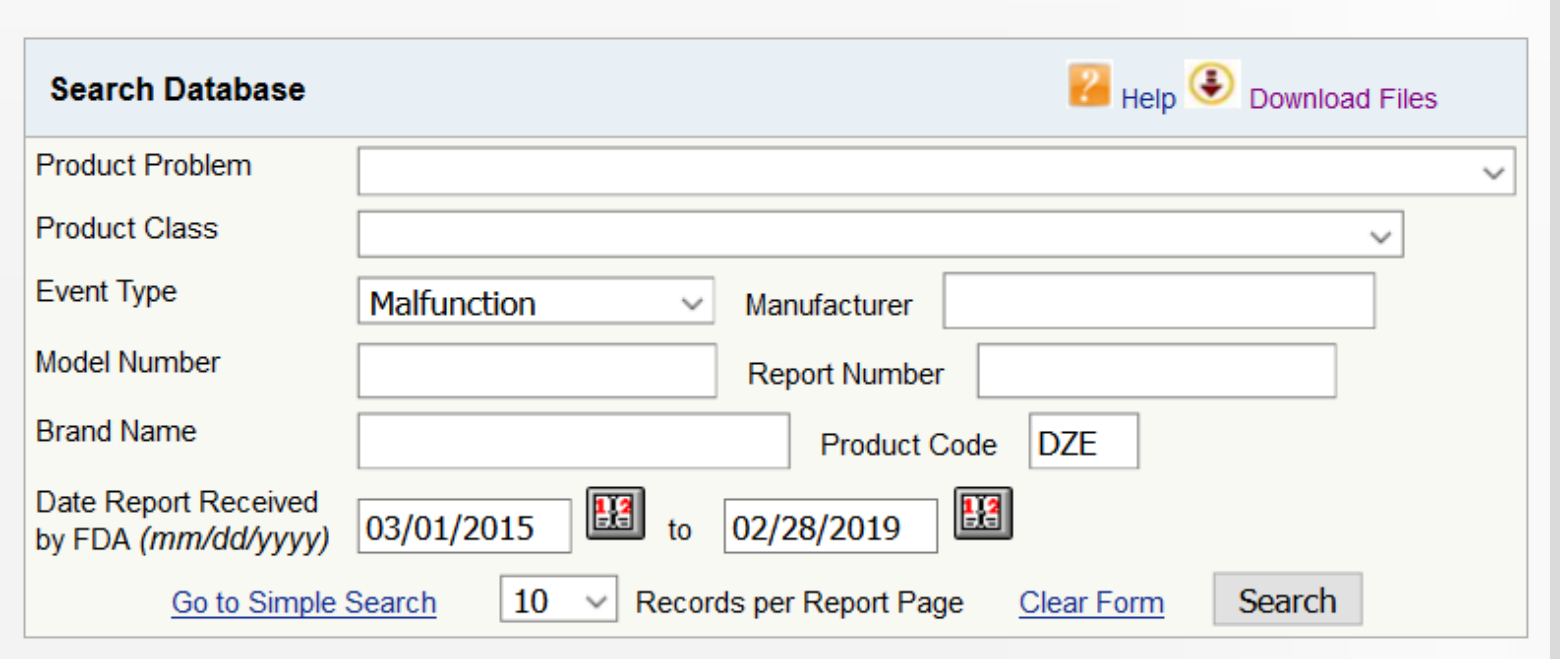


MAUDE

- Important notes:
  - Reports are redacted
  - “Download Files” feature best for data more than 10 years old



Example Search



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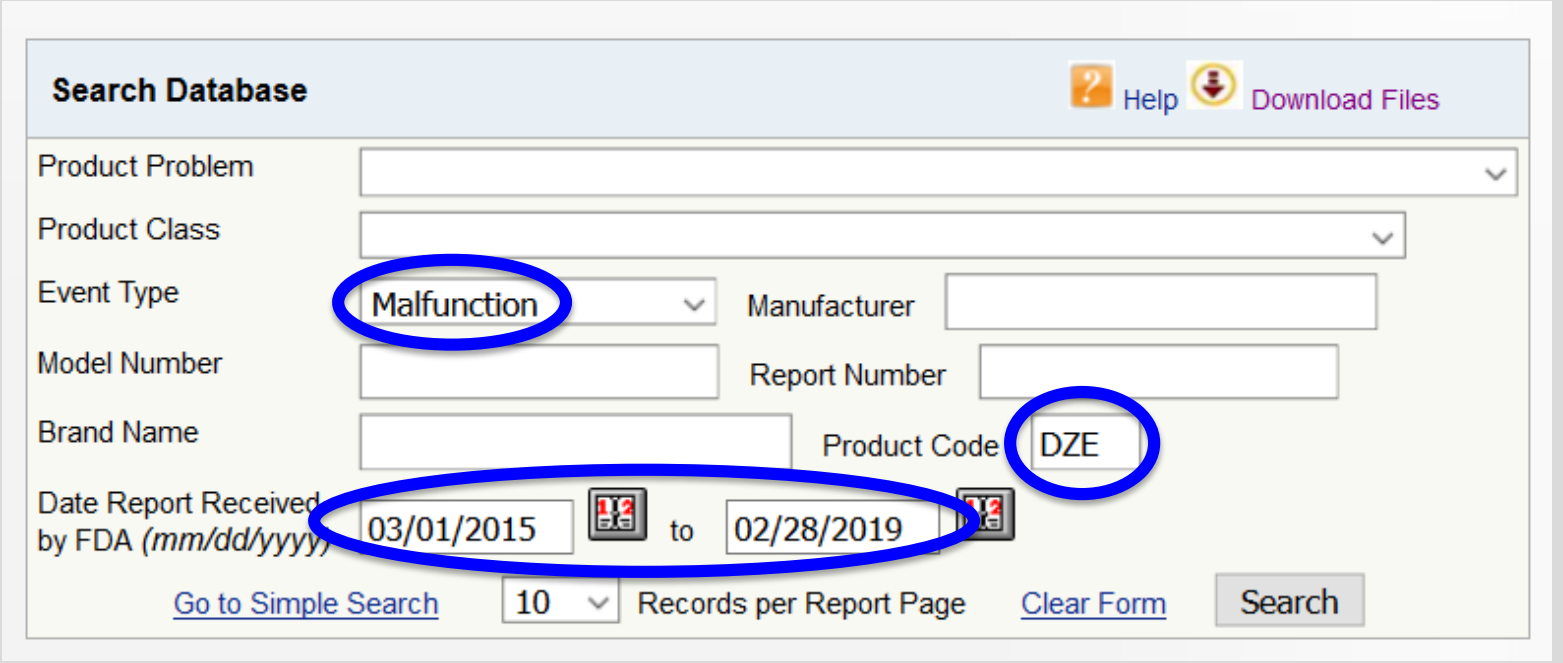

Product Code Classification Database

Example Search

1 2 3 4 5 6 7 8 9 10 >

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

New Search | Export to Excel | Help

Manufacturer	Brand Name	Date Report Received
PRISMATIK DENTALCRAFT, INC.	HAHN TAPERED IMPLANT Ø4.3 X 13 MM	01/31/2019
PRISMATIK DENTALCRAFT, INC.	HAHN TAPERED IMPLANT Ø3.5 X 10 MM	01/31/2019
NOBEL BIOCARE USA, LLC	NOBELACTIVE INTERNAL RP 4.3X11.5MM	01/31/2019
PRISMATIK DENTALCRAFT, INC.	HAHN TAPERED IMPLANT Ø4.3 X 10 MM	01/30/2019
BIOMET 3I	DRIVER	01/30/2019
PRISMATIK DENTALCRAFT, INC.	INCLUSIVE TAPERED IMPLANT 4.7 MMD X 8 MM	01/28/2019
PRISMATIK DENTALCRAFT, INC.	INCLUSIVE TAPERED IMPLANT 3.7 MMD X 11.5	01/28/2019
PRISMATIK DENTALCRAFT, INC.	INCLUSIVE TAPERED IMPLANT 4.2 MMD X 10 M	01/28/2019
PRISMATIK DENTALCRAFT, INC.	INCLUSIVE TAPERED IMPLANT 3.2 MMD X 8 MM	01/28/2019
ZIMMER DENTAL	SCR REPLACE FRICTION-FIT GOLD & TI ABUT	01/28/2019

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Example Search

PRISMATIK DENTALCRAFT, INC. HAHN TAPERED IMPLANT Ø4.3 X 13 MM Back to Search Results

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

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: 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

Your Call to Action

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


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