Navigating the MAUDE Database

FDA Small Business Regulatory Education for Industry (REdI)

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Fariba Maramkhah
Consumer Safety Officer
Division of Regulatory Programs 3
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Value of Manufacturer and User Facility Device Experience (MAUDE)

- **FDA**:
  - Monitor device performance
  - Detect potential device-related safety issues
  - Contribute to benefit-risk assessments

- **Consumers and Industry:**
  - Understand device safety and performance
  - Design improvement

Learning Objectives

- Define Manufacturer and User Facility Device Experience (MAUDE)
- Identify two different options to search Medical Device Reports (MDRs)
- Demonstrate how to search for MDRs

Manufacturer and User Facility Device Experience (MAUDE)

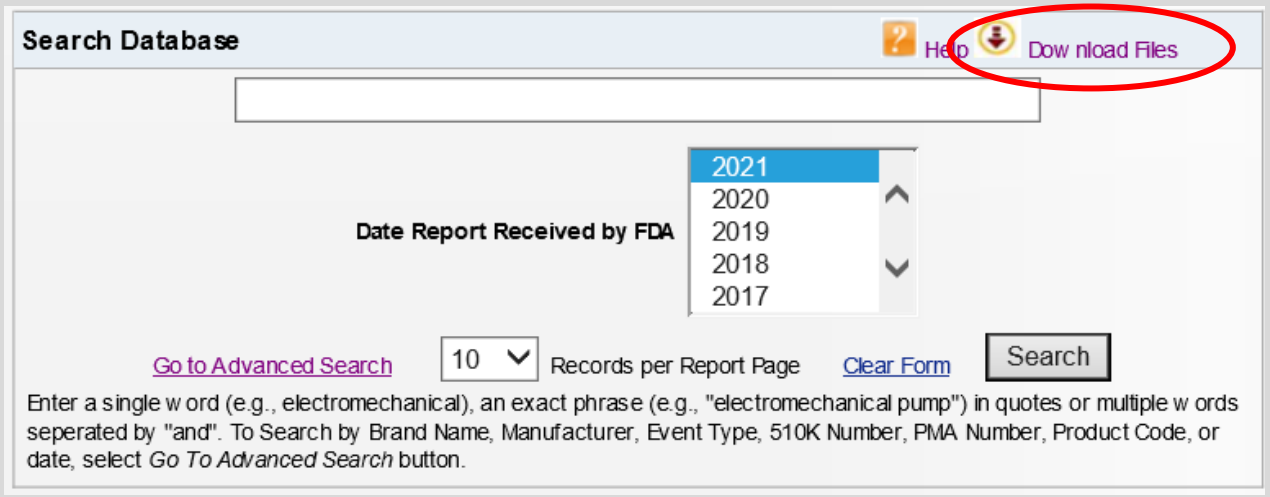
MAUDE

- **Publicly searchable database:**

  Adverse event medical device reports
- **Mandatory Reports**
  - Manufacturers
  - User facilities
  - Importers
- **Voluntary Reports**
  - Health Care Professionals
  - Patients and Consumers

MAUDE

- Reports are within the past 10 years
- Reports received more than 10 years ago are available



- Updated monthly

Page Last Updated: 04/30/2021
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

MAUDE

Important Note

- Reports are redacted:
  - Trade secret, confidential business information => (b)(4)
  - Personnel or medical files information => (b)(6)

FOIA Exemptions

Redacted Report

Example 1

Catalog Number EMC2421P
Device Problems Delivered as Unsterile Product (1421); Device Contamination with Chemical or Other Material (2944)
Patient Problem No Clinical Signs, Symptoms or Conditions (4582)
Event Date 03/18/2021
Event Type Malfunction
Manufacturer Narrative
Initial reporter address: (b)(6). Should additional relevant information become available, a supplemental report will be submitted.

Example 2

Event Description
Boston scientific received information that this patient was upgraded to a cardiac resynchronization therapy defibrillator (crt-d) system on (b)(6) 2016. On (b)(6) 2016, the patient was hospitalized for pericardial effusion and shock due to cardiac tamponade. It was suspected that the right atrial (ra) and left ventricular (lv) leads had perforated the heart. A surgical revision was performed and the ra and lv leads were explanted. The patient experienced electromechanical dissociation and cerebral hemorrhaging following surgery and passed away. The leads are not expected to be returned. There were no allegations against the right ventricular (rv) lead and the model and serial information was not provided.

MAUDE

- MAUDE database is organized primarily by reports
- Reports not included in MAUDE:
  - CDRH's legacy Device Experience Network (DEN)
  - Alternative Summary Reporting Program
  - These reports are available in Download Data Files

Knowledge Check

What kind of reports does the MAUDE database house?

A. Medical Device Reports (MDRs)

B. Exemptions and Variances

C. FDA Guidance Documents

Medical Device Reports (MDRs)
Search Options

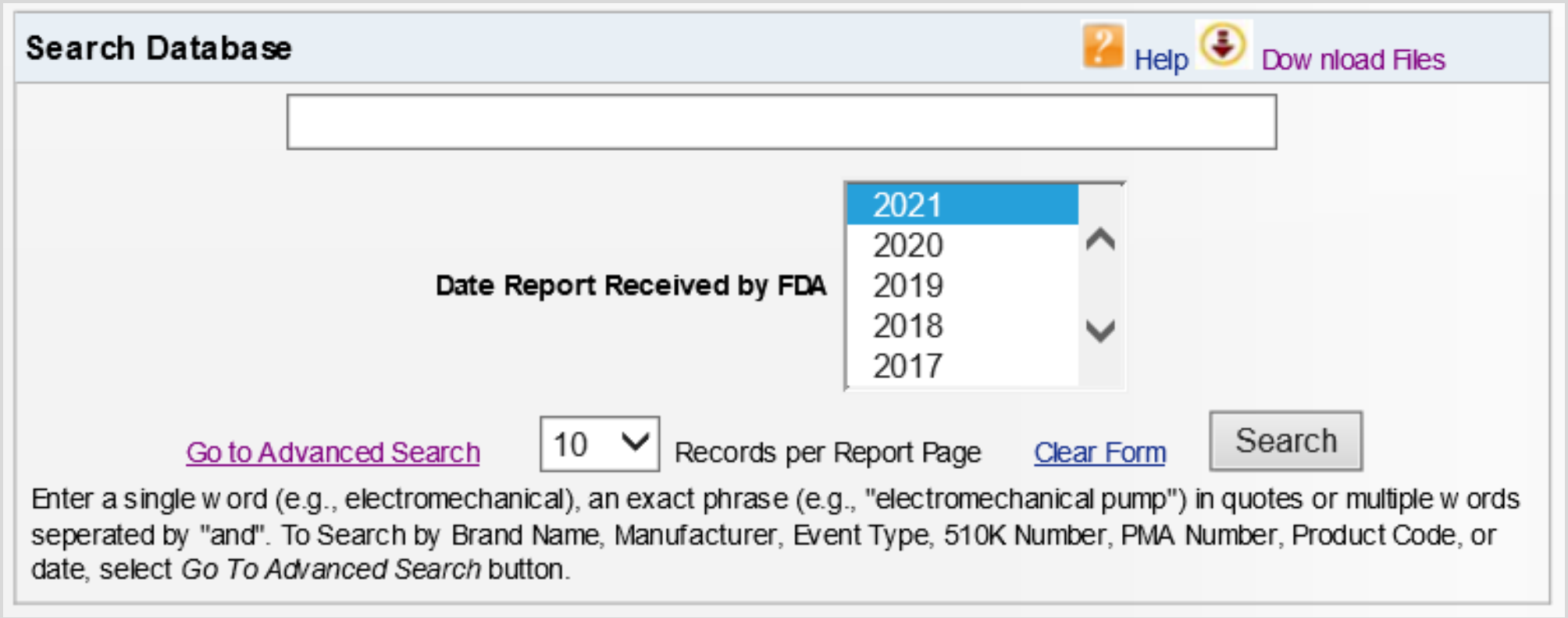
MAUDE Search Options

Two choices for searching:

- **Simple Search:**
  - Searches for terms and keywords
- **Advanced Search:**
  - Searches by Brand Name, Manufacturer, Product Code, etc.
  - Selects specific fields
  - Builds a more complex search

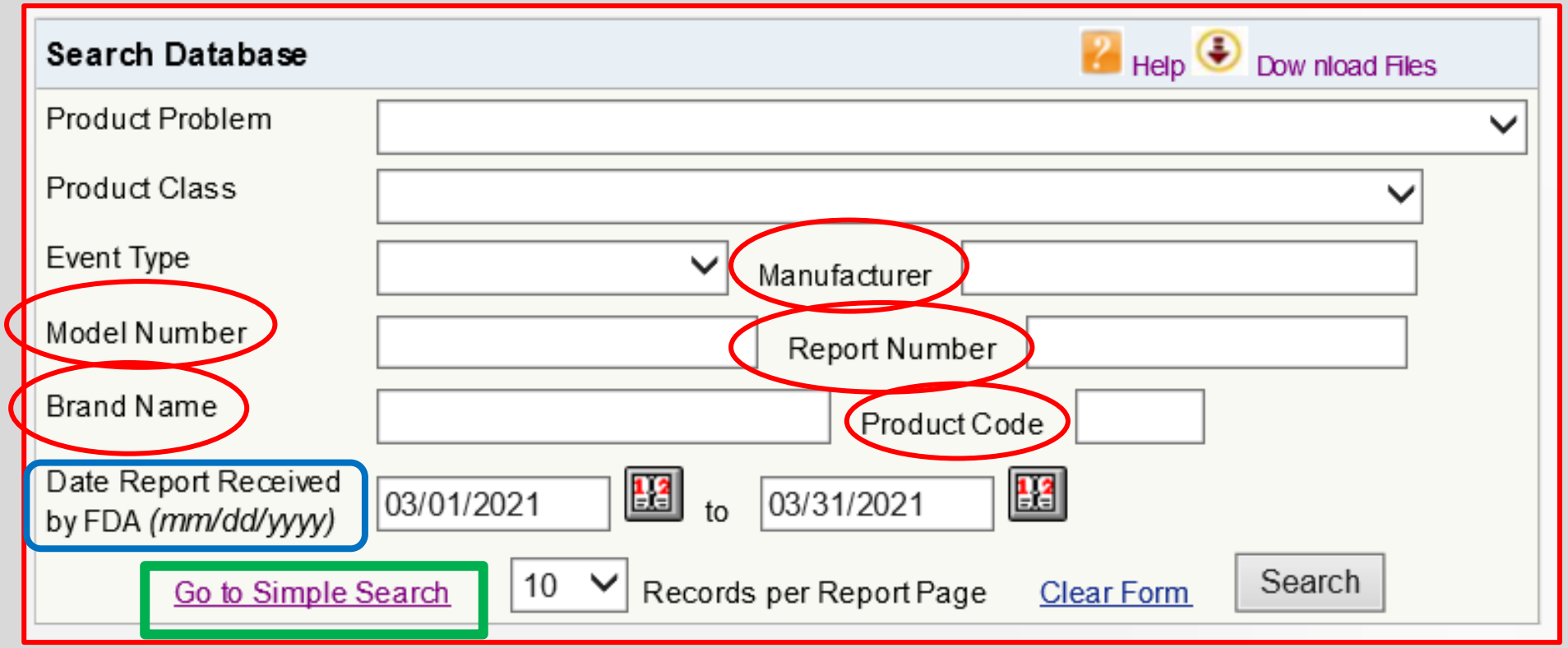
MAUDE Search Options

- **Simple Search:**



MAUDE Search Options

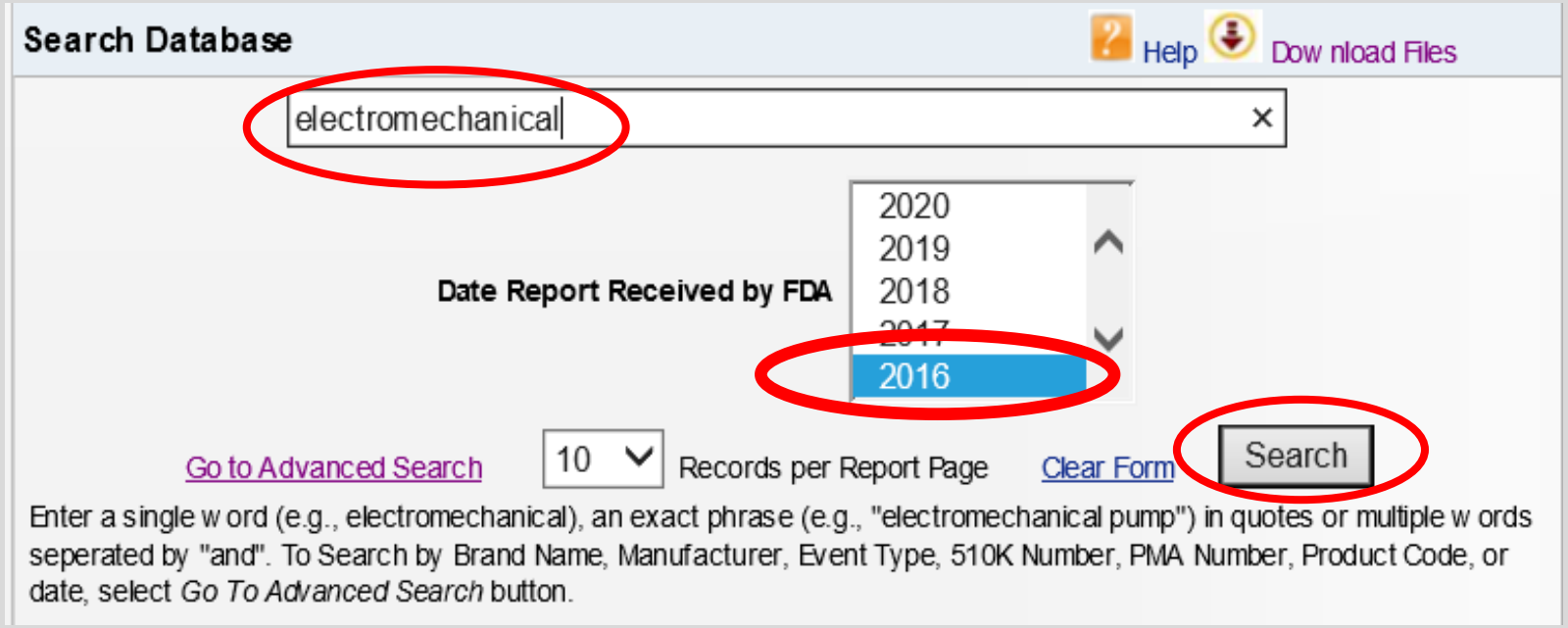
- **Advanced Search:**



How to Search for MDRs

Example: Simple Search

1. Open MAUDE database
2. Enter a single word or an exact phrase in quotes
3. Select the year you would like to search in the “Date Report Received by FDA” dropdown menu
4. Click the “Search” button



Example: Simple Search

View:

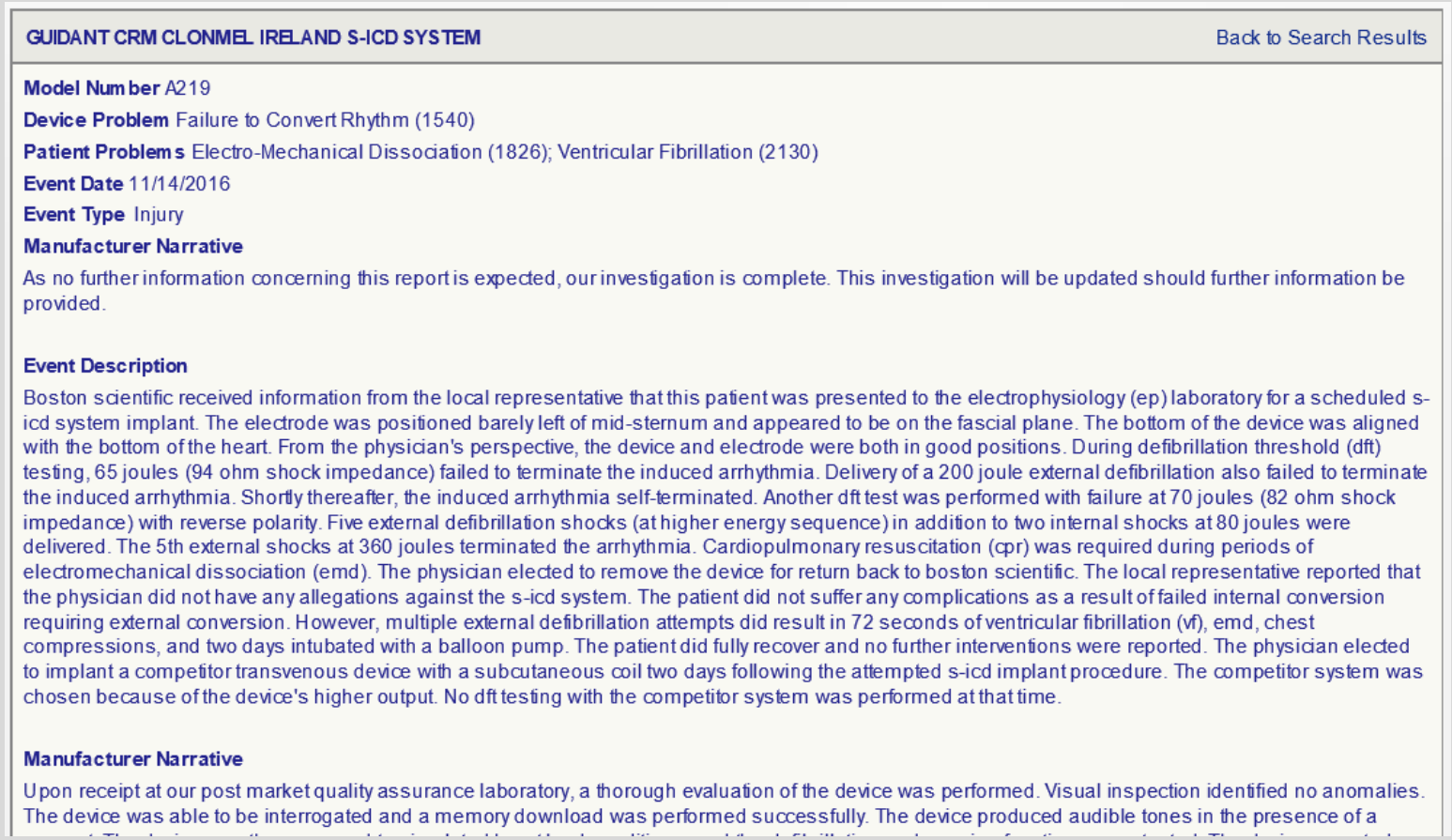
- 33 MDRs
- Print/bookmark/ email
- Export
- Help button

Manufacturer	Brand Name	Date Received
GUIDANT CRM CLONMEL IRELAND	S-ICD SYSTEM	12/21/2016
BOSTON SCIENTIFIC - COSTA RICA (COYOL)	AMPLATZ SUPER STIFF GUIDEWIRE	12/20/2016
MEDTRONIC IRELAND	RESOLUTE INTEGRITY RX	12/15/2016
MEDTRONIC IRELAND	RESOLUTE INTEGRITY RX	12/15/2016
MEDTRONIC IRELAND	RESOLUTE INTEGRITY RX	12/15/2016
MEDTRONIC PUERTO RICO OPERATIONS CO	EVERA XT DR	12/09/2016
MDT PUERTO RICO OPERATIONS CO	SYNCHROMED II	12/08/2016
DEVILBISS HEALTHCARE LLC	DEVILBISS SUCTION UNIT WITH CANISTER	12/01/2016
MEDTRONIC, INC.	MARINR	11/30/2016
MDT PUERTO RICO OPERATIONS CO	SYNCHROMED II	11/28/2016

Example: Simple Search

View:

- Device Model Number
- Device Problem
- Patient Problem
- Event Description



GUIDANT CRM CLONMEL IRELAND S-ICD SYSTEM — Back to Search Results

Model Number A219

Device Problem Failure to Convert Rhythm (1540)

Patient Problems Electro-Mechanical Dissociation (1826); Ventricular Fibrillation (2130)

Event Date 11/14/2016

Event Type Injury

Manufacturer Narrative

As no further information concerning this report is expected, our investigation is complete. This investigation will be updated should further information be provided.

Event Description

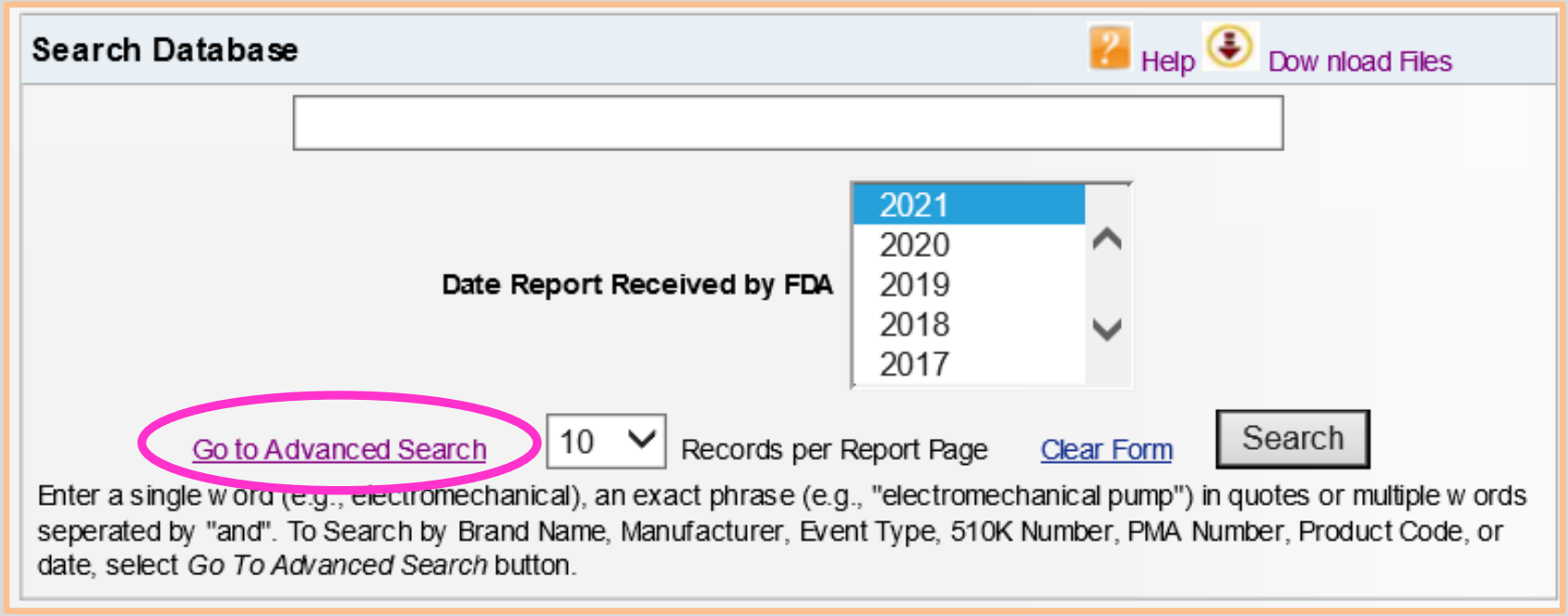
Boston scientific received information from the local representative that this patient was presented to the electrophysiology (ep) laboratory for a scheduled s-icd system implant. The electrode was positioned barely left of mid-sternum and appeared to be on the fascial plane. The bottom of the device was aligned with the bottom of the heart. From the physician's perspective, the device and electrode were both in good positions. During defibrillation threshold (dft) testing, 65 joules (94 ohm shock impedance) failed to terminate the induced arrhythmia. Delivery of a 200 joule external defibrillation also failed to terminate the induced arrhythmia. Shortly thereafter, the induced arrhythmia self-terminated. Another dft test was performed with failure at 70 joules (82 ohm shock impedance) with reverse polarity. Five external defibrillation shocks (at higher energy sequence) in addition to two internal shocks at 80 joules were delivered. The 5th external shocks at 360 joules terminated the arrhythmia. Cardiopulmonary resuscitation (cpr) was required during periods of electromechanical dissociation (emd). The physician elected to remove the device for return back to boston scientific. The local representative reported that the physician did not have any allegations against the s-icd system. The patient did not suffer any complications as a result of failed internal conversion requiring external conversion. However, multiple external defibrillation attempts did result in 72 seconds of ventricular fibrillation (vf), emd, chest compressions, and two days intubated with a balloon pump. The patient did fully recover and no further interventions were reported. The physician elected to implant a competitor transvenous device with a subcutaneous coil two days following the attempted s-icd implant procedure. The competitor system was chosen because of the device's higher output. No dft testing with the competitor system was performed at that time.

Manufacturer Narrative

Upon receipt at our post market quality assurance laboratory, a thorough evaluation of the device was performed. Visual inspection identified no anomalies. The device was able to be interrogated and a memory download was performed successfully. The device produced audible tones in the presence of a

Example: Advanced Search

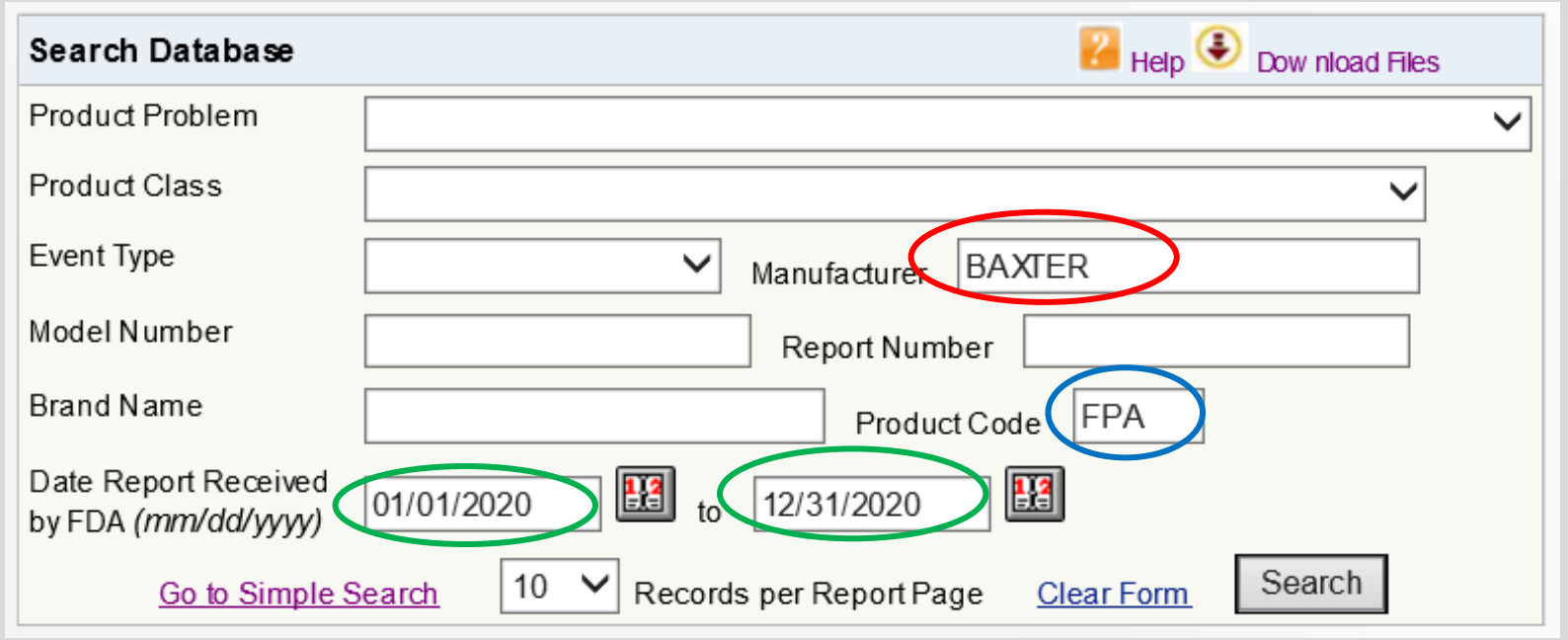
- Open the MAUDE database
- Select, “Go To Advanced Search”



MAUDE Database

Example: Advanced Search

- Input selected search parameters:
  - Manufacturer
  - Product Code
  - Date Report received by FDA



[Product Code Classification Database]

Example: Advanced Search

- View search results obtained:
  - Number of records matching search
  - Date Reports Received

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.

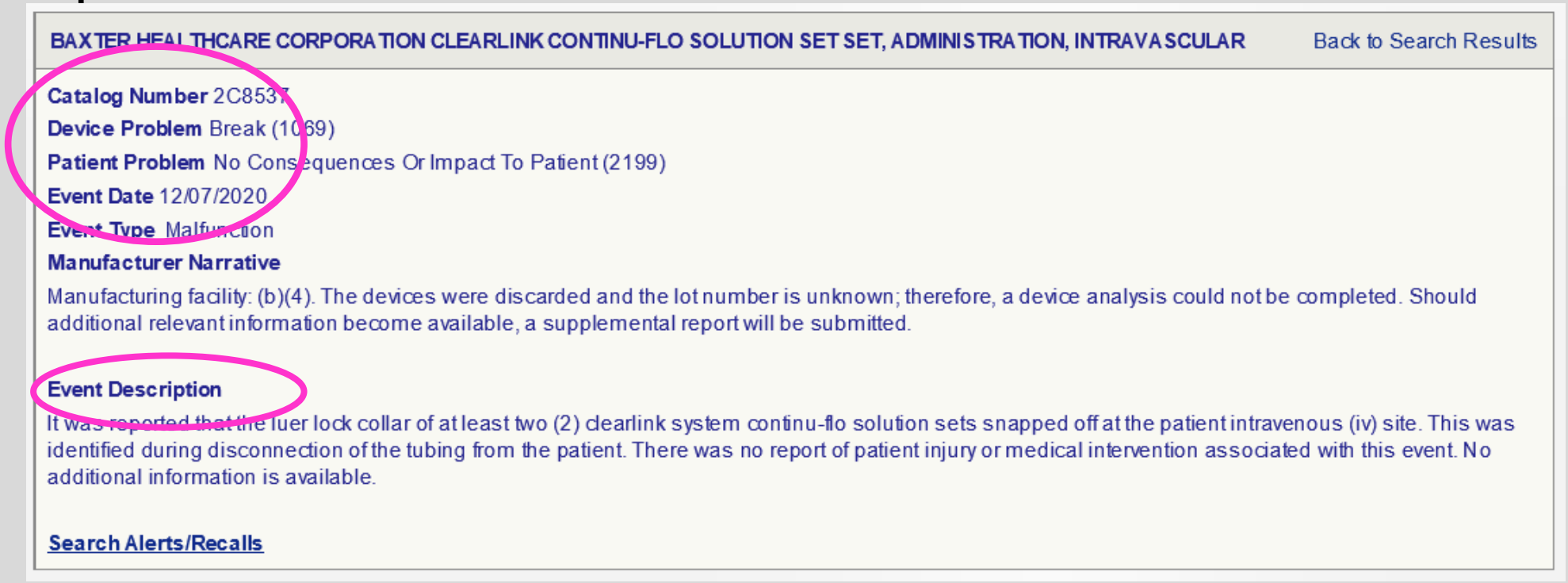
New Search | Export to Excel | Help

Manufacturer	Brand Name	Date Report Received
BAXTER HEALTHCARE CORPORATION	CLEARLINK CONTINU-FLO SOLUTION SET	12/30/2020
BAXTER HEALTHCARE CORPORATION	CLEARLINK DUO-VENT CONTINU-FLO SOLUTION	12/30/2020
BAXTER HEALTHCARE CORPORATION	ONE-LINK NEUTRAL LUER ACTIVATED DEVICE	12/30/2020
BAXTER HEALTHCARE CORPORATION	EXTENSION SETS WITH ONE-LINK NEEDLE-FREE	12/30/2020
BAXTER HEALTHCARE CORPORATION	CLEARLINK CONTINU-FLO SOLUTION SET	12/30/2020
BAXTER HEALTHCARE CORPORATION	BURETROL SOLUTION SETS	12/30/2020
BAXTER HEALTHCARE CORPORATION	BURETROL SOLUTION SETS	12/30/2020
BAXTER HEALTHCARE CORPORATION	BURETROL SOLUTION SETS	12/30/2020
BAXTER HEALTHCARE CORPORATION	I.V. ADMINISTRATION SETS WITH CONTROL-A-	12/29/2020
BAXTER HEALTHCARE CORPORATION	EXTENSION SETS WITH ONE-LINK NEEDLE-FREE	12/29/2020

Example: Advanced Search

View:

- Catalog Number, Device Problem, Patient Problem, Event Description



BAXTER HEALTHCARE CORPORATION CLEARLINK CONTINU-FLO SOLUTION SET SET, ADMINISTRATION, INTRAVASCULAR Back to Search Results

Catalog Number 2C8537
Device Problem Break (1069)
Patient Problem No Consequences Or Impact To Patient (2199)
Event Date 12/07/2020
Event Type Malfunction
Manufacturer Narrative

Manufacturing facility: (b)(4). The devices were discarded and the lot number is unknown; therefore, a device analysis could not be completed. Should additional relevant information become available, a supplemental report will be submitted.

Event Description

It was reported that the luer lock collar of at least two (2) clearlink system continu-flo solution sets snapped off at the patient intravenous (iv) site. This was identified during disconnection of the tubing from the patient. There was no report of patient injury or medical intervention associated with this event. No additional information is available.

Search Alerts/Recalls

Knowledge Check

What is the "Download Files" button used for?

A. To get more details on reports

B. To locate missing data

C. To access reports more than 10 years old

Summary

- MAUDE database houses medical device adverse events reports
- Reports are publicly available
- Reports can be retrieved through Simple Search or Advanced Search
- Simple Search searches for all terms
- Advanced Search allows you to use a variety of criteria in combination

Contact Information

Division of Industry and Consumer Education (DICE)

- **Email:** DICE@fda.hhs.gov
- **Phone:** 1(800) 638-2041 or (301) 796-7100
- **Web:** www.fda.gov/DICE

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