MAUDE

MAUDE Information Available to the Public

Databases

- Two databases are available for searching
  - MAUDE
    - All recent and future reports found here.
    - Website and downloadable files can be searched.
    - The examples shown later use MAUDE.
  - MDR
    - Old reports found here.
    - Only the website search is available.

What You Get

- MAUDE:
  - Manufacturer Information
  - Adverse Event Information
  - Device Information
  - Patient Outcome
- MDR:
  - Minimal event information

MAUDE

- MAUDE - Manufacturer and User Facility Device Experience
- Reports of adverse events involving medical devices.
  - Voluntary reports since June 1993,
  - User facility reports since 1991
  - Distributor reports since 1993
  - Manufacturer reports since August 1996.
  - May not include reports made according to exemptions, variances, or alternative reporting requirements.
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

MAUDE

- Website Search
  - Simple: Word/phrase/year
  - Advanced: More options
  - Searches based on what the report contains.
  - Good for the public at large.
- Downloadable Files
  - Zipped pipe delimited files with no headers.
  - Table descriptions on website.
  - Tables linked by an event, report, and device event key.
  - Good for researchers and public health officials.

MDR

- MDR - Medical Device Reporting
- Search for incidents that were received by FDA from 1984 to before July 31, 1996
- Website Search Only
  - Simple: Word/phrase and year
  - Advanced: More options
  - Searches based on what the report contains.
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm

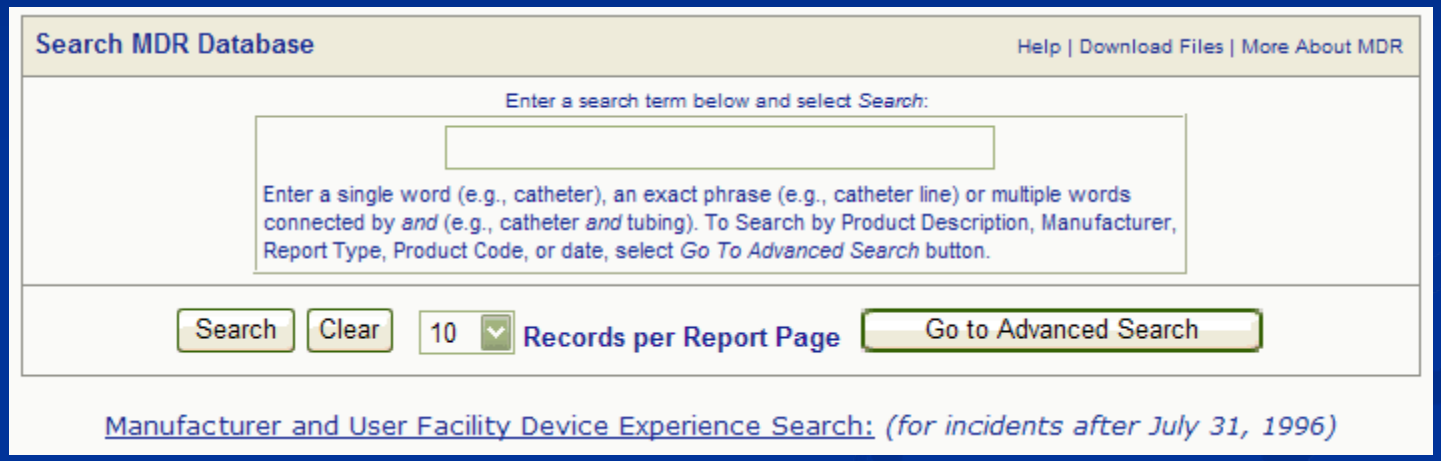
What You See

- Information From Reporter
  - Submitted by reporter.
  - Value Showing No Information (MAUDE only)
    - ASKU – asked but unknown
    - NI – no information; answer could be available, but no information was provided
    - NA – not applicable; this question does not apply to the situation
    - Adding these values are more descriptive than leaving the data blank.
  - Shown if information is releasable – meaning personal information described in the event has been redacted.

Limitations

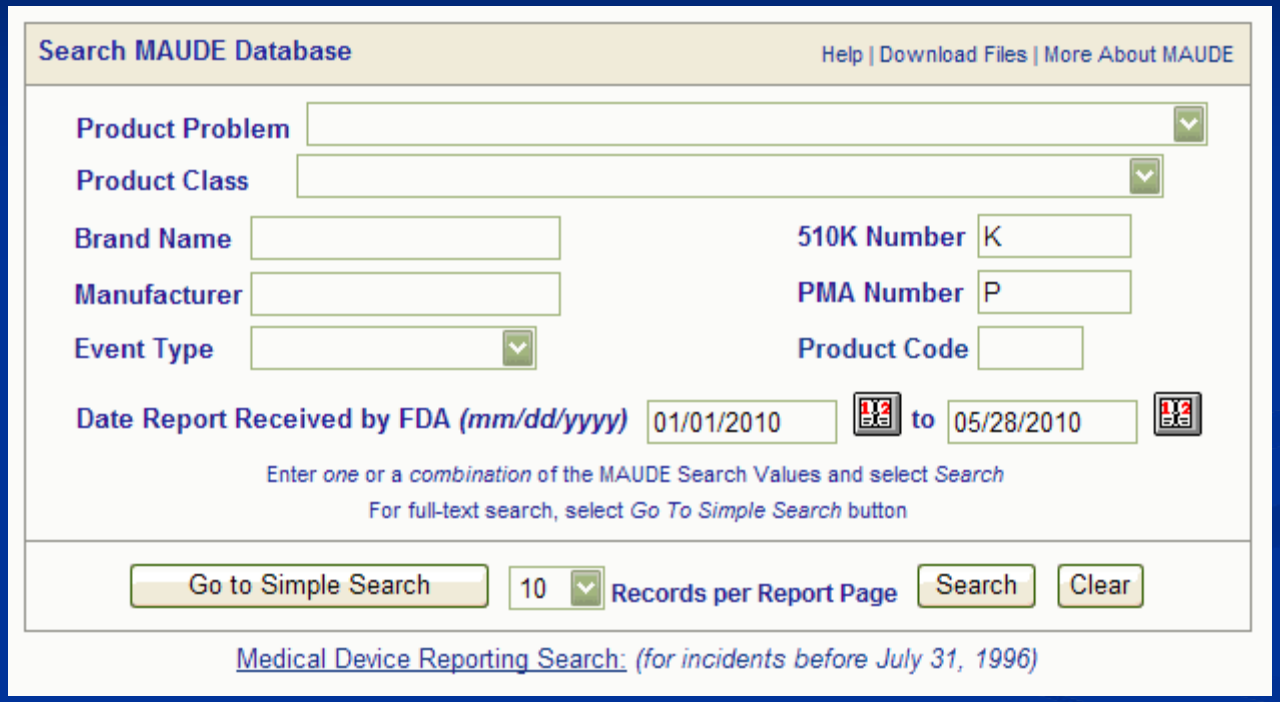
- Only redacted text in the database.
  - So not yet redacted text in reports will not be present.
- MAUDE Updated once a month (usually on the 6th).
- May be more than one report for an event.

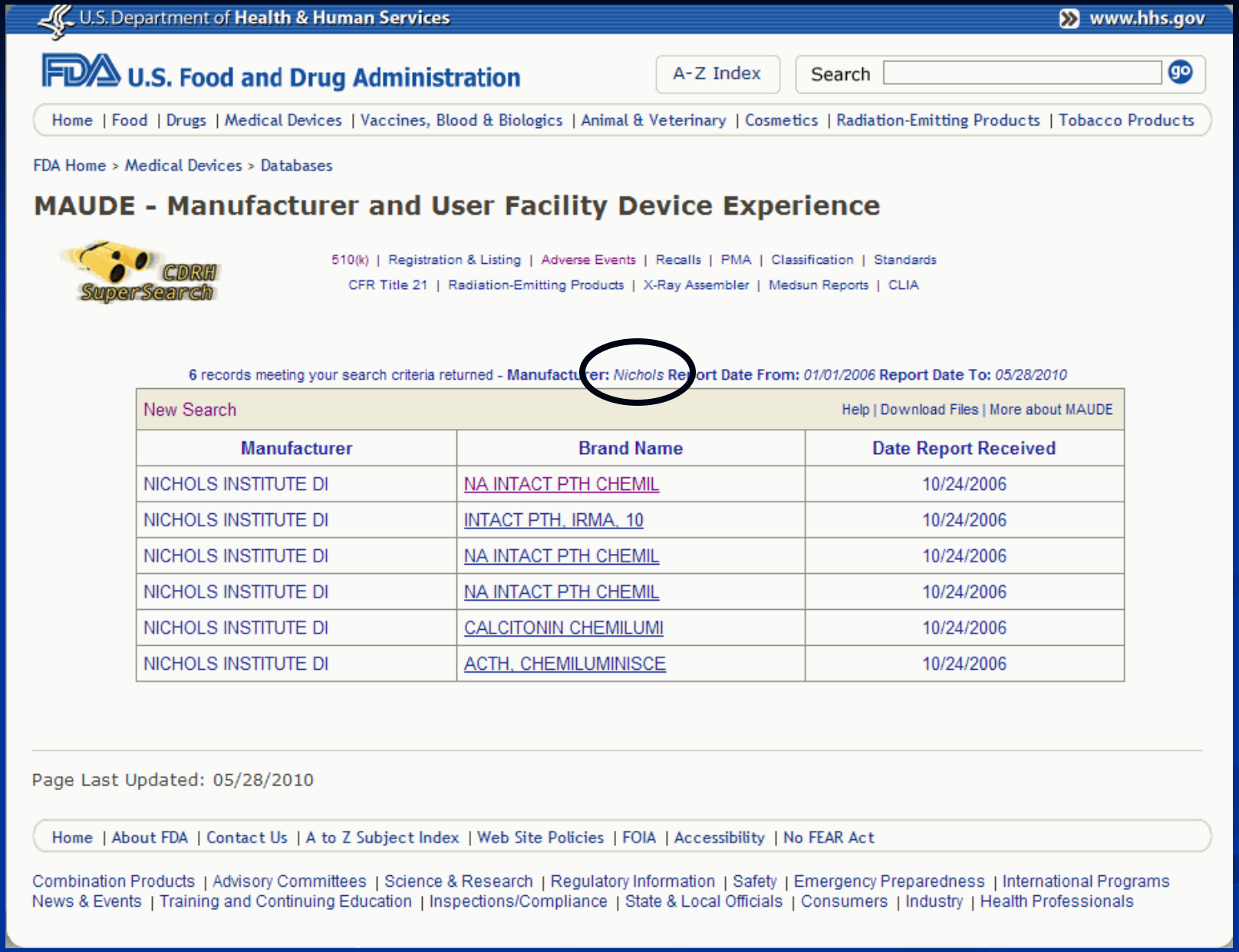
Examples In MAUDE


Search MDR Database
Help | Download Files | More About MDR
Enter a search term below and select Search:
Enter a single word (e.g., catheter), an exact phrase (e.g., catheter line) or multiple words connected by and (e.g., catheter and tubing). To Search by Product Description, Manufacturer, Report Type, Product Code, or date, select Go To Advanced Search button.
Search
Clear
10
Records per Report Page
Go to Advanced Search
Manufacturer and User Facility Device Experience Search: (for incidents after July 31, 1996)


Search MDR Database
Help | Download Files | More About MDR
Enter one or a combination of the MDR Search Values and select Search
MDR Search Values
Product Description
Manufacturer
Product Code
Report Type
Date Report Received by FDA (mm/dd/yyyy)
to
For full-text search, select Go To Simple Search button
Search
Clear
10
Records per Report Page
Go to Simple Search
Manufacturer and User Facility Device Experience Search: (for incidents after July 31, 1996)


Search MAUDE Database
Help | Download Files | More About MAUDE
Enter a search term below, choose a date range and select Search
Date Report Received by FDA
(press CTRL key for multiple years)
2010
2009
2008
2007
2006
Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To Search by Brand Name, Manufacturer, Event Type, 510K Number, PMA Number, Product Code, or date, select Go To Advanced Search button.
Go to Advanced Search
10
Records per Report Page
Search
Clear
Medical Device Reporting Search: (for incidents before July 31, 1996)


Search MAUDE Database
Help | Download Files | More About MAUDE
Product Problem
Product Class
Brand Name
Manufacturer
Event Type
510K Number
K
PMA Number
P
Product Code
Date Report Received by FDA (mm/dd/yyyy)
01/01/2010
to
05/28/2010
Enter one or a combination of the MAUDE Search Values and select Search
For full-text search, select Go To Simple Search button
Go to Simple Search
10
Records per Report Page
Search
Clear
Medical Device Reporting Search: (for incidents before July 31, 1996)



U.S. Department of Health & Human Services www.hhs.gov

U.S. Food and Drug Administration

A-Z Index | Search | go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

FDA Home > Medical Devices > Databases

MAUDE - Manufacturer and User Facility Device Experience

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

6 records meeting your search criteria returned - **Manufacturer:** *Nichols* **Report Date From:** *01/01/2006* **Report Date To:** *05/28/2010*

New Search | Help | Download Files | More about MAUDE

Manufacturer	Brand Name	Date Report Received
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	INTACT PTH, IRMA, 10	10/24/2006
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	CALCITONIN CHEMILUMI	10/24/2006
NICHOLS INSTITUTE DI	ACTH, CHEMILUMINISCE	10/24/2006

Page Last Updated: 05/28/2010

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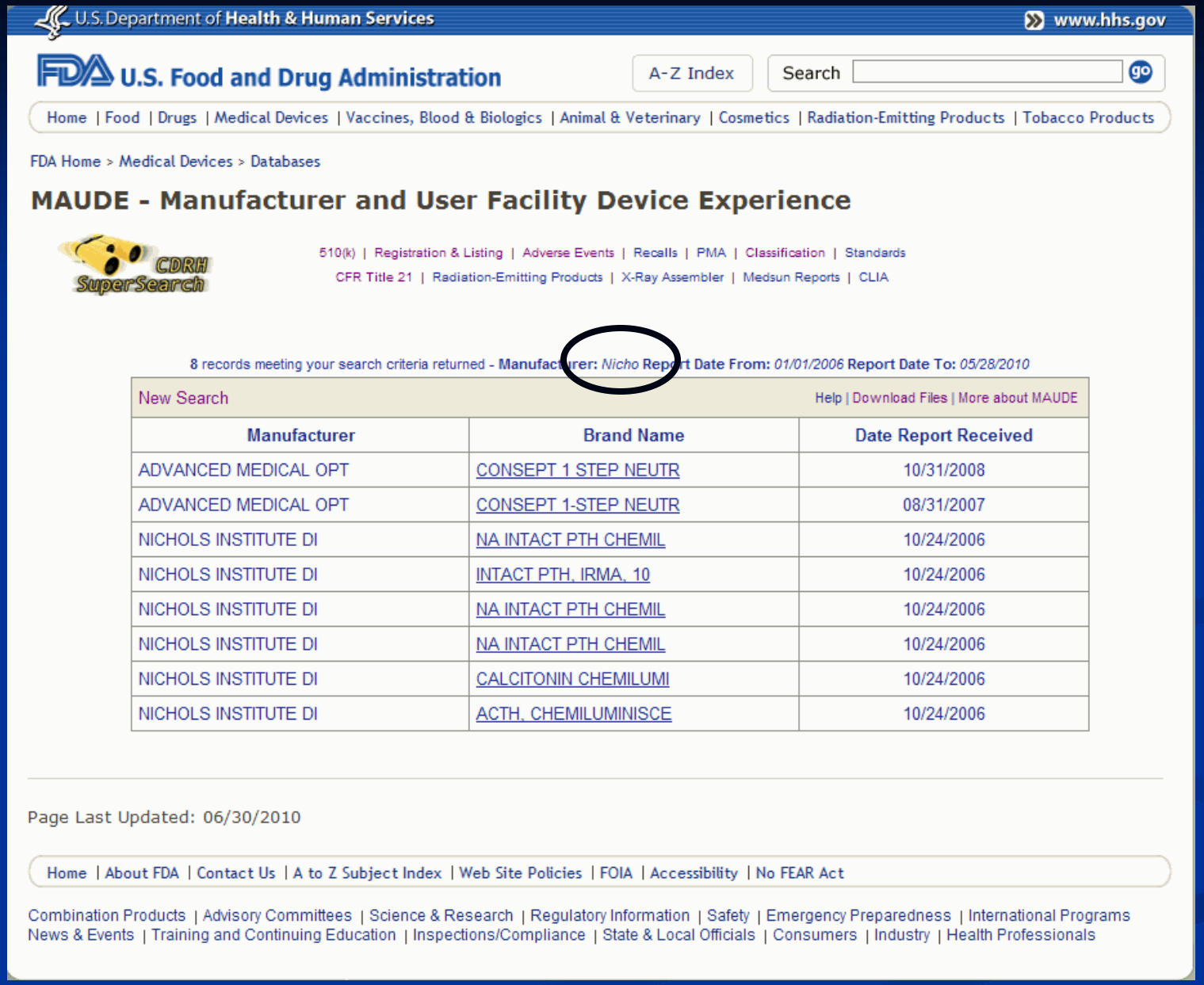
News & Events | Training and Continuing Education | Inspections/Compliance | State & Local Officials | Consumers | Industry | Health Professionals


U.S. Department of Health & Human Services
www.hhs.gov
U.S. Food and Drug Administration
A-Z Index
Search
Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products
FDA Home > Medical Devices > Databases
MAUDE - Manufacturer and User Facility Device Experience
CDRH SuperSearch
510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA
8 records meeting your search criteria returned - Manufacturer: Nicho Report Date From: 01/01/2006 Report Date To: 05/28/2010
New Search
Help | Download Files | More about MAUDE
Manufacturer
Brand Name
Date Report Received
ADVANCED MEDICAL OPT
CONSEPT 1 STEP NEUTR
10/31/2008
ADVANCED MEDICAL OPT
CONSEPT 1-STEP NEUTR
08/31/2007
NICHOLS INSTITUTE DI
NA INTACT PTH CHEMIL
10/24/2006
NICHOLS INSTITUTE DI
INTACT PTH, IRMA, 10
10/24/2006
NICHOLS INSTITUTE DI
NA INTACT PTH CHEMIL
10/24/2006
NICHOLS INSTITUTE DI
NA INTACT PTH CHEMIL
10/24/2006
NICHOLS INSTITUTE DI
CALCITONIN CHEMILUMI
10/24/2006
NICHOLS INSTITUTE DI
ACTH, CHEMILUMINISCE
10/24/2006
Page Last Updated: 06/30/2010
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Combination Products | Advisory Committees | Science & Research | Regulatory Information | Safety | Emergency Preparedness | International Programs
News & Events | Training and Continuing Education | Inspections/Compliance | State & Local Officials | Consumers | Industry | Health Professionals

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

FDA Home > Medical Devices > Databases

MAUDE - Manufacturer and User Facility Device Experience

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

New Search

No records were found with
Manufacturer: *Nicholse* **Report Date From:** *01/01/2006* **Report Date To:** *05/28/2010*

Page Last Updated: 05/28/2010

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News & Events | Training and Continuing Education | Inspections/Compliance | State & Local Officials | Consumers | Industry | Health Professionals

New Search

Help | Download Files | More about MAUDE

Manufacturer	Brand Name	Date Report Received
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	INTACT PTH, IRMA, 10	10/24/2006
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	NA INTACT PTH CHEMIL	10/24/2006
NICHOLS INSTITUTE DI	CALCITONIN CHEMILUMI	10/24/2006
NICHOLS INSTITUTE DI	ACTH, CHEMILUMINISCE	10/24/2006

NICHOLS INSTITUTE DIAGNOSTICS NA INTACT PTH CHEMILUMINESCENCE KIT INTACT PARATHYROID HORMONE (PTH)

Back to Search Results

Catalog Number 60-7022
Event Date 09/01/2005
Event Type Injury; Patient Outcome Hospitalization;
Manufacturer Narrative
Product labeling states: "assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions." Nid has ceased information operations and no longer markets this product.

Event Description
Patient alleged that she underwent unnecessary surgery (parathyroidectomy) following laboratory testing.

Search Alerts/Recalls

New Search | Submitan Adverse Event Report

Brand Name	NA INTACT PTH CHEMILUMINESCENCE KIT
Type of Device	INTACT PARATHYROID HORMONE (PTH)
Generic Brand Name	NA INTACT PTH CHEMILUMINESCENCE KIT
Generic Generic Name	INTACT PARATHYROID HORMONE (PTH)
Generic Catalogue Number	60-7022
Manufacturer (Section D)	NICHOLS INSTITUTE DIAGNOSTICS 1311 Calle Batido San Clemente CA 92673
Manufacturer Contact	Jill Ghalani, Director 1311 Calle Batido San Clemente, CA 92673 (949)940-7482
Device Event Key	792019
MDR Report Key	774298
Event Key	799299
Report Number	2050093-2006-00003
Device Sequence Number	1
Product Code	CEW
Report Source	Manufacturer
Source Type	Other
Reporter Occupation	Patient
Type of Report	Initial
Report Date	09/01/2005
If Device Was Involved in the Event	
If Patient Was Involved in the Event	
Date FDA Received	10/24/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	60-7022
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	09/01/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	No Answer Provided
Type of Device Usage	Unknown

Patient TREATMENT DATA

Date Received: 10/24/2006 Patient Sequence Number: 1

#	Treatment	Treatment Date
1 UNK		

NICHOLS INSTITUTE DIAGNOSTICS NA INTACT PTH CHEMILUMINESCENSE KIT INTACT PARATHYROID HORMONE (PTH)

Back to Search Results

Catalog Number 62-7022

Event Date 08/02/2005

Event Type Injury **Patient Outcome** Hospitalization;

Manufacturer Narrative

Product labeling states: "assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions. " nid has ceased information operations and no longer markets this product.

Event Description

Patient alleged that she underwent unnecessary surgery (parathyroidectomy) following laboratory testing.

Search Alerts/Recalls

New Search Submit an Adverse Event Report

Brand Name NA INTACT PTH CHEMILUMINESCENSE KIT

Type of Device INTACT PARATHYROID HORMONE (PTH)

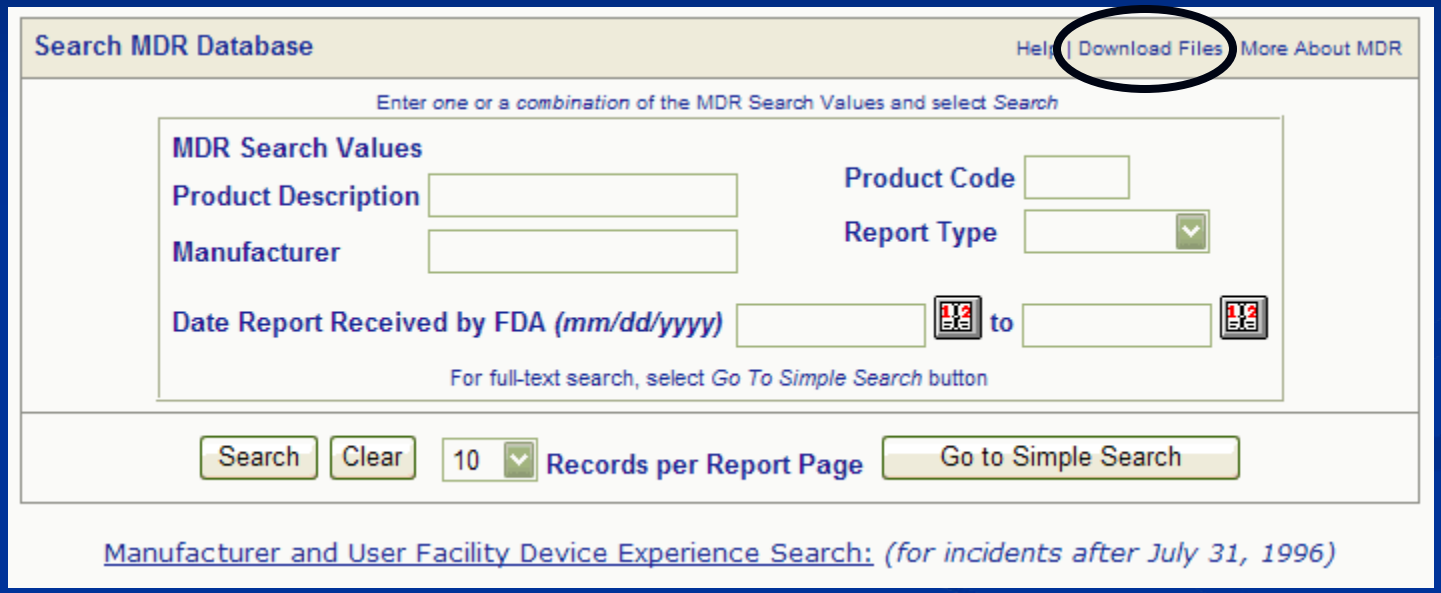
Brand Name	NA INTACT PTH CHEMILUMINESCENSE KIT
Type of Device	INTACT PARATHYROID HORMONE (PTH)
Baseline Brand Name	NA INTACT PTH CHEMILUMINESCENSE KIT
Baseline Generic Name	INTACT PARATHYROID HORMONE (PTH)
Baseline Catalogue Number	62-7022
Manufacturer *(Section D)*	NICHOLS INSTITUTE DIAGNOSTICS 1311 Calle Batido San Clemente CA 92673
Manufacturer Contact	Anil Bhalani, Director 1311 Calle Batido San Clemente , CA 92673 (949) 940 -7465
Device Event Key	762018
MDR Report Key	774238
Event Key	738338
Report Number	2050095-2006-00002
Device Sequence Number	1
Product Code	CEW
Report Source	Manufacturer
Source Type	Other

Source Type	Other
Reporter Occupation	Patient
Type of Report	Initial
Report Date	09/01/2005
***1* Device Was Involved in the Event**	
***1* Patient Was Involved in the Event**	
Date FDA Received	10/24/2006
Is This An Adverse Event Report?	Yes
Is This A Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	62-7022
Was Device Available For Evaluation?	No
Is The Reporter A Health Professional?	No
Was the Report Sent to FDA?	No
Date Manufacturer Received	09/01/2005
Was Device Evaluated By Manufacturer?	Device Not Returned To Manufacturer
Is The Device Single Use?	No
Is this a Reprocessed and Reused Single-Use Device?	No
Is the Device an Implant?	No
Is this an Explanted Device?	No Answer Provided
Type of Device Usage	Unkown

Patient TREATMENT DATA

Date Received: 10/24/2006 Patient Sequence Number: 1

#	Treatment	Treatment Date
1,UNK		


Search MDR Database
Help | Download Files | More About MDR
Enter one or a combination of the MDR Search Values and select Search
MDR Search Values
Product Description
Manufacturer
Product Code
Report Type
Date Report Received by FDA (mm/dd/yyyy)
to
For full-text search, select Go To Simple Search button
Search
Clear
10
Records per Report Page
Go to Simple Search
Manufacturer and User Facility Device Experience Search: (for incidents after July 31, 1996)

Device Advice: Device Regulation and Guidance

Postmarket Requirements (Medical Devices)

Reporting Adverse Events (Medical Devices)

- Manufacturer and User Facility Device Experience Database - (MAUDE)
- Amendments to the MDR Regulation to Implement FDAMA Changes
- eMDR – Electronic Medical Device Reporting

Manufacturer and User Facility Device Experience Database - (MAUDE)

MAUDE data represents reports of adverse events involving medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. MAUDE may not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19.

An **on-line search** is available which allows you to search the CDRH's database information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE is scheduled to be updated quarterly and the search page reflects the date of the most recent update. FDA seeks to include all reports received prior to the update. However, the inclusion of some reports may be delayed by technical or clerical difficulties.

MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

Please be aware that reports regarding device trade names may have been submitted under different manufacturer names. Searches only retrieve records that contain the search term(s) provided by the requester.

The data is also available in zipped files for downloading. The data is updated on a quarterly basis.

These files were then compressed ("zipped") in order to save space. For these files to be useful to you, you'll first have to download them, unzip them, and then import them into a database or word processor for your further processing.

> **DISCLAIMER:** Section 21 CFR 803.16 states that "A report or other information submitted by a reporting entity under this part, and any release by FDA of that report or information, does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, or the reporting entity or its employees, caused or contributed to the reportable event. The reporting entity need not admit and may deny that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a reportable event." In addition, some firms have submitted their own additional disclaimer statements. A file of those disclaimers will be placed on the web shortly.

The releasable MAUDE data is presented in four logical records types. For this data to be meaningful, you should download all four types of files. The four record formats contain all releasable information on MEDWATCH Form 3500.

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
mdrfoi.zip	4896KB	38325KB	128931	MAUDE Base records received to date for 2010
mdrfoiadd.zip	1271KB	10467KB	35064	New MAUDE Base records for the current month.
mdrfoichange.zip	1311KB	10319KB	34493	MAUDE Base data updates: changes to existing Base data.
mdrfoithru2009.zip	52464KB	352811KB	1309977	Master Record through 2009
patient.zip	651KB	3814KB	120953	MAUDE Patient records received to date for 2010
patientadd.zip	152KB	900KB	31044	New MAUDE Patient records for the current month.
patientchange.zip	167KB	945KB	30431	MAUDE Patient data updates: changes to existing Base data.
patientthru2009.zip	7844KB	42620KB	1301544	Patient Record through 2009
deviceproblemcodes.zip	10KB	27KB	975	Device Data for problemcodes
deviceproblemtest.zip	12KB	31KB	982	Device Data for problemtest
foidev.zip	4461KB	26559KB	129364	Device Data for foidev
foidev1998.zip	3396KB	17539KB	63441	Device Data for foidev1998
foidev1999.zip	2928KB	14799KB	52882	Device Data for foidev1999
foidev2000.zip	2984KB	15161KB	53298	Device Data for foidev2000
foidev2001.zip	3221KB	16283KB	58069	Device Data for foidev2001
foidev2002.zip	3411KB	17265KB	65810	Device Data for foidev2002
foidev2003.zip	3578KB	17953KB	67845	Device Data for foidev2003
foidev2004.zip	3070KB	14887KB	57057	Device Data for foidev2004
foidev2005.zip	4698KB	24668KB	93441	Device Data for foidev2005
foidev2006.zip	6493KB	34460KB	134600	Device Data for foidev2006
foidev2007.zip	5952KB	31959KB	149443	Device Data for foidev2007
foidev2008.zip	5543KB	32970KB	164992	Device Data for foidev2008
foidev2009.zip	7707KB	45943KB	222523	Device Data for foidev2009
foidevadd.zip	1165KB	7499KB	35115	New MAUDE Device data for the current month.
foidevchange.zip	1188KB	7429KB	34599	Device data updates: changes to existing Device data and additional Device data for existing Base records.

```
1742901|1654057|2015691-2010-13649|M|Y|1|1|06/30/2010|Y|N|06/01/2010|05/31/2010|N|001|Y|U|||||||0
1742829|1654008|1742829|U|N|1|1|06/28/2010|N|N|06/25/2010|06/23/2010||500|*|Y|||||||I|06/25/2010
1742826|1654005|2015691-2010-13648|M|Y|1|1|06/30/2010|N|Y|06/15/2010|06/15/2010|N|000||N|||||||06
1742823|1654003|2015691-2010-13647|M|Y|1|1|06/30/2010|N|Y|06/08/2010|06/08/2010|N|000|N|*|||||||0
1742807|1653983|2939204-2010-00764|M|Y|1|1|06/30/2010|Y|N|06/10/2010||001|Y|*|||||||I||||N|||4
1742805|1648514|2015691-2010-13646|M|Y|1|1|06/30/2010|N|Y|06/07/2010|06/03/2010|N|000|N|*|||||||0
1742804|1653981|2939204-2010-00796|M|Y|1|1|06/30/2010|Y|Y|06/24/2010|06/23/2010|N|001|Y|*|||||||||
```

MDRFOI file contains following 75 fields, delimited by pipe (|), one record per line:

1. MDR Report Key
2. Event Key
3. Report Number
4. Report Source Code

    P = Voluntary report
    U = User Facility report
    D = Distributor report
    M = Manufacturer report

5. Manufacturer Link Flag (internal information flag)
6. Number Devices in Event (if source code is 'P', field will be null)
7. Number Patient in Event (if source code is 'P', field will be null)
8. Date Received

SECTION-B

9. Adverse Event Flag (B1)
10. Product Problem Flag (B1)
11. Date Report (B4)
12 Date of Event (B3) -- new added, 2006
13 Single Use Flag (Reprocessor Flag) (D8) -- new added, 2006
14 Reporter Occupation Code (E3) -- new added, 2006

SECTION-E (if source code is 'P', Section E to H will contain no data)

15. Health Professional (E2)
16. Initial Report to FDA (E4)

    Y = Yes
    N = No
    U = Unknown
    * = No answer provided

SECTION-F

17. Distributor Name (F3) -- if report source code = 'M' and Manufacturer link flag is 'Y', fields 14 - 20 will contain data; otherwise they will be null
18. Distributor Address line 1 (F3)
19. Distributor Address line 2 (F3)
20. Distributor City (F3)
21. Distributor State Code (F3)
22. Distributor Zip Code (F3)
23. Distributor Zip Code Ext (F3)
24. Date Facility Aware (F6)
25. Type of Report (F7) !multiple submission type, separate by ','

    I = Initial submission
    F = Followup
    X = Extra copy received
    O = Other information submitted

In Summary

- MAUDE
  - Where recent and future information resides.
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfmAdvanced
  - Both web search and downloadable files available.
- MDR
  - Where old report information resides.
  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMDR/Search.cfm
  - Web search only.