MedSun
Medical Product Safety Network
KidNet
FDA

KidNet Roundtable

May 15, 2008
1:00-2:00PM EDT

Adverse Event of Fire with an Infant Oxygen Head Hood

- An infant resting in a bassinet, under an infant warmer, had an oxygen hood in place. The oxygen hood was placed over the infant's head and was attached to an oxygen air blender for administration of 100% oxygen. As staff approached the bassinet, they observed a flash of flames under the oxygen hood. Staff removed the hood and removed the oxygen from the wall, extinguishing the fire with a blanket.

Infant Oxygen Head Hoods

- **What is it?**
  - a clear plastic hood that fits over an infant's head
  - different designs and sizes, some with potential ports for monitoring gas content
- **What is it used for?**
  - to deliver a constant concentration of oxygen
  - as support in cases of
    - mild respiratory distress syndrome (RDS)
    - transient tachypnea of the newborn (TTN)
    - meconium aspiration
    - neonatal pneumonia

Infant Oxygen Head Hoods

- Can be placed on infants in cribs, radiant warmers or incubators
- May be used along with nasal cannula to increase inspired oxygen content
- Oxygen is warmed and humidified, which can lead to fogging and limits visibility

Oxygen Content within the Hood

- Inspired oxygen content within the hood depends on:
  - Flow of oxygen
    - If too low, less delivered oxygen is available to the infant due to infiltration of environmental gas (21% oxygen on room air)
    - Remember, higher gas flows help wash out exhaled carbon dioxide
  - Concentration of oxygen
    - Reliable delivery of concentrations of 60% or less
    - Possible to deliver higher concentrations with higher flows and tighter seals

Oxygen Delivery via Infant Head Hoods

- A blender system is considered the most reliable way to deliver fixed oxygen concentration
  - Make sure to use the appropriate sized hood
  - Too large, the infant can slip out of the hood and oxygen may be diluted by leaks
  - Too small, infant may develop pressure points around the neck

Oxygen Delivery via Infant Head Hoods

- Monitor delivered oxygen concentrations by continuous or intermittent sampling (at least every hour) and record them.

- Calibrate oxygen monitors and analyzers to room air and 100% oxygen level every 8 hours or by hospital/product protocol.

Infant Oxygen Hood Considerations

- **Advantages**
  - Oxygen can be warmed and humidified without pressure
  - Hoods can be used for infants of various sizes in different types of beds
  - Good for short term use (a few days maximum)

Infant Oxygen Hood Considerations

- **Disadvantages**
  - oxygen content of inspired gas may vary with hood position, amount of leakage and movement of the infant out from under the hood
  - Noise levels may be high when liter flow is high
  - Caregiver ability to visualize the infant's face maybe be obscured due to fogging or condensation
  - Carbon dioxide buildup if flow is low and the hood is well sealed and risk of positive pressure creation if the hood is well sealed and the gas flow is high
  - High levels of humidity and condensation increase the risk of infection when hoods are used for extended periods.

Troubleshooting Tips

- If an infant experiences a desaturation, apneic, or bradycardic episode, check for:
  - Is the oxygen delivery system in place and functioning properly?
  - Is the infant under the oxygen hood?
  - Are the appropriate oxygen concentrations and flow rates being delivered?
  - Is the infant positioned properly? Infants can be in either the prone or supine position as long as proper monitoring is undertaken. Prone positioning has been shown to improve oxygenation.

Additional Tips

- Given that oxygen is a drug, some form of continuous monitoring of the infant's oxygenation (e.g., arterial blood gases, pulse oximetry) is needed for optimal therapy.
- Humidify delivered oxygen as dry gases are irritating to the airways. Replace humidifiers and tubing per institutional/product protocol to prevent respiratory therapy equipment from being a source of infection.

References

- Gardner, Sandra & Gerald Merenstein. Handbook of Neonatal Intensive Care. St. Louis : Mosby, 2002.

- St. Clair, Nancy, Suzanne Touch and Jay Greenspan. "Supplemental Oxygen Delivery to the Nonventilated Neonate." Neonatal Network. Sep. 2001: 39-46.

Adverse Event of Fire Involving an Infant Incubator

- While preparing to transport an infant to the intensive care nursery, an odor was noted by the MD and smoke was noted to be coming from the front of the isolette.
- The infant was removed without harm. Biomed evaluation found the jack on the power chassis assembly had overheated and melted.
- Biomed replaced the subassembly to fix the unit and pro-actively replaced the same subassembly on a second unit.
- The reporter indicates the incident may be age related since the units were purchased in 1981 and 1991 respectively and are still in use.

Adverse Events involving Fire with Incubators and Warmers

- An infant radiant warmer bed battery pack making a ‘strange noise’ with emission of smoke during transport from the delivery room to the NICU. The infant was removed from the warmer and the O2 being delivered to the patient was turned off.

- An infant warmer was in use in the NICU for about 2 hours when a burning odor was noticed and smoke was observed coming from the top of the unit. No mention of patient injury. Follow-up reveals the power supply module was found to have fairly significant damage coming from components within the board. The components were replaced.

Lessons Learned from Adverse Events

- Use incubators and warmers according to manufacturer labeling and instructions for use.
- Make sure to use appropriate power cords and connections for the device, including batteries and battery packs.
- Regularly inspect power cords and connections to make sure they are not frayed, loose, or showing signs of heat wear or damage (i.e. signs of melting).
- Monitor oxygen delivery devices for proper function while in use.
- Schedule routine device/equipment inspections and adhere to a clearly defined maintenance/service plan to assure functional integrity of the device.

Recently Reported Adverse Event with Monitors

- GE Dash 4000 monitor display spontaneously goes blank or blacks out while in use on NICU patients. The displays remain off despite multiple attempts by clinicians. RN's unable to view ECG tracings and other hemodynamics on NICU patients. GE has provided loaner Dash 4000's during the time of the hospital's reported problem.

Recently Reported Adverse Event with Monitors

- Follow-up with the firm resulted in the firm's issuance of a product information letter to chiefs of nursing, directors of biomedical engineering and healthcare administrators.
- The letter alerts users to the display becoming unusable after several years of continuous operating service life.

Adverse Event Evaluation

- Reports are individually triaged to identify actual or potential risk to public health requiring priority review and follow-up

- Examples of high-risk events include events of :
  - pediatric deaths
  - multiple patient deaths or serious injuries
  - death involving
    - Fire , Explosion, Electrocution
    - Burn, Anaphylaxis, Exsanguination

Adverse Event Evaluation

Reports are then reviewed against previously submitted adverse event reports:

- In the MedSun database that contains reports received from other MedSun facilities
- In the MAUDE (Manufacturer and User Facility Device Experience database) that contains reports submitted by manufacturers, consumers, and user facilities (including MedSun) to further understand reported device problems

Adverse Event Evaluation

- A check of pre-market approval or clearance information is checked to obtain labeling and instructions for use
- Looking at the clinical and scientific literature reviews for information on the occurrence of similar problems with the device
- Independent safety research organization data may be researched to gain additional perspectives, i.e., ECRI, ISMP

Adverse Event Evaluation

Reviewers may request additional information about an individual event or a group of similar events by:

- Contacting the manufacturer, user facility or voluntary reporter via:
  - telephone, fax, letter, or e-mail
- Working with other CDRH Offices to arrange:
  - a manufacturing facility inspection to see how the device is made and how product complaints are handled
  - a user facility visit to talk with those involved in the adverse event
- Consulting with other FDA Centers to obtain additional perspectives on reported problems

Adverse Event Outcomes

- All data related to the adverse event are reviewed to determine if and what type of FDA action should be undertaken. Outcomes of adverse event evaluations include:
  - **Education and Outreach**
    - Articles in peer-reviewed clinical journals and Newsletters
    - Presentations at conferences
  - **Research Initiatives**
    - Initiation of surveys to further characterize device use in clinical settings
    - Partnering with organizations to create or access device-related adverse event registries
    - Working with standards organizations to develop or refine device standards
  - **Public Health Notifications**
    - Safety Alerts, CDRH web postings
  - **Regulatory Actions**
    - Recalls

Update on FDA Actions in Response to Heparin Adverse Events

- FDA Update on Contaminated Heparin
- http://www.fda.gov/cder/drug/infopage/heparin/default.htm#healthcare

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Searching the Public Maude and MedSun Databases

Public Medical Device Adverse Event Databases

- Two public databases are available for searching medical device adverse event reports submitted to the FDA
- MedSun reports through MedSun's Online Newsletter access via:

  http://www.fda.gov/cdrh/medsun/index.html
- Manufacturer, voluntary, and all user facility reports (including MedSun) through Public Maude access via:

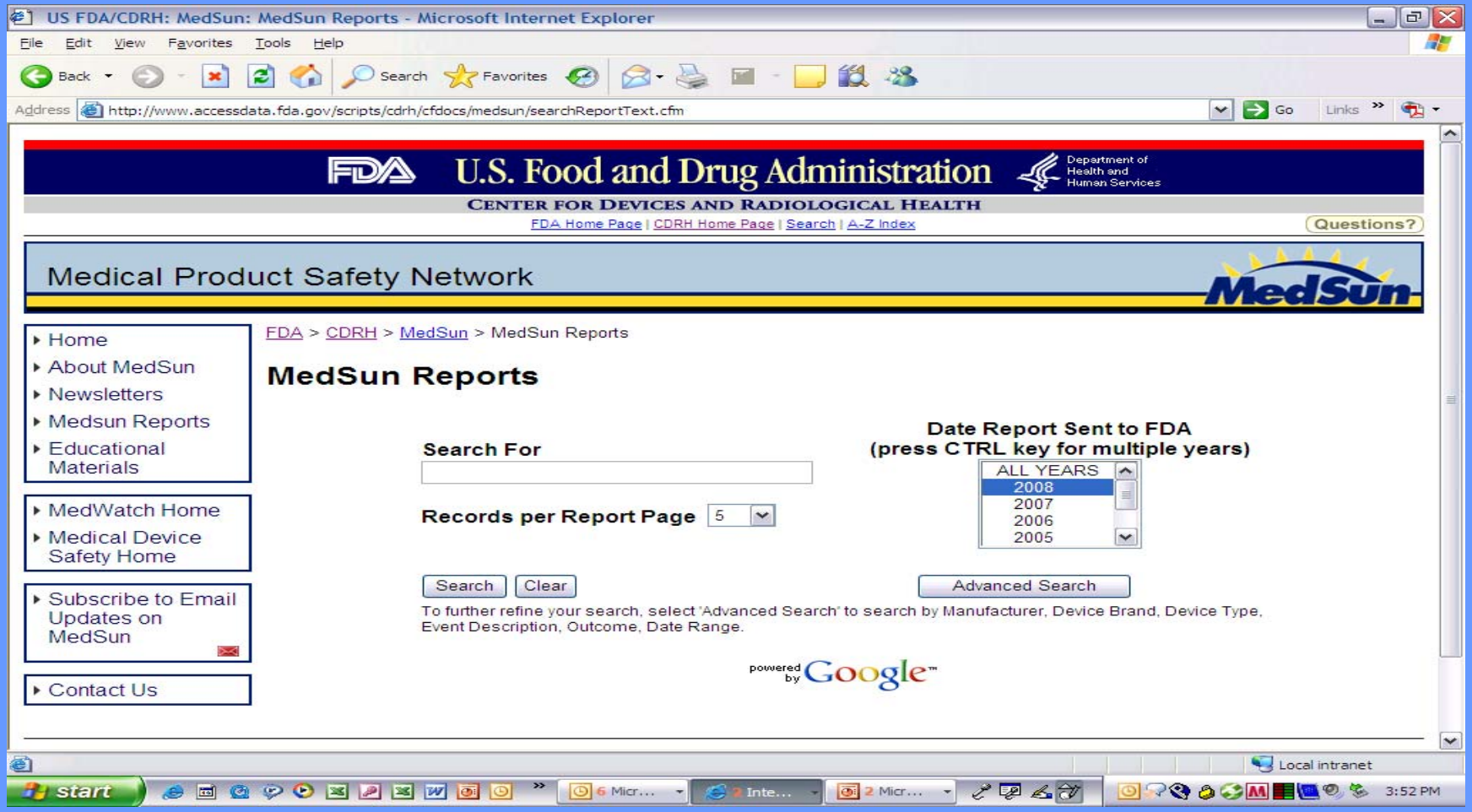
  http://www.fda.gov/cdrh/maude.html

Searching the MedSun Database from the MedSun Online Newsletter

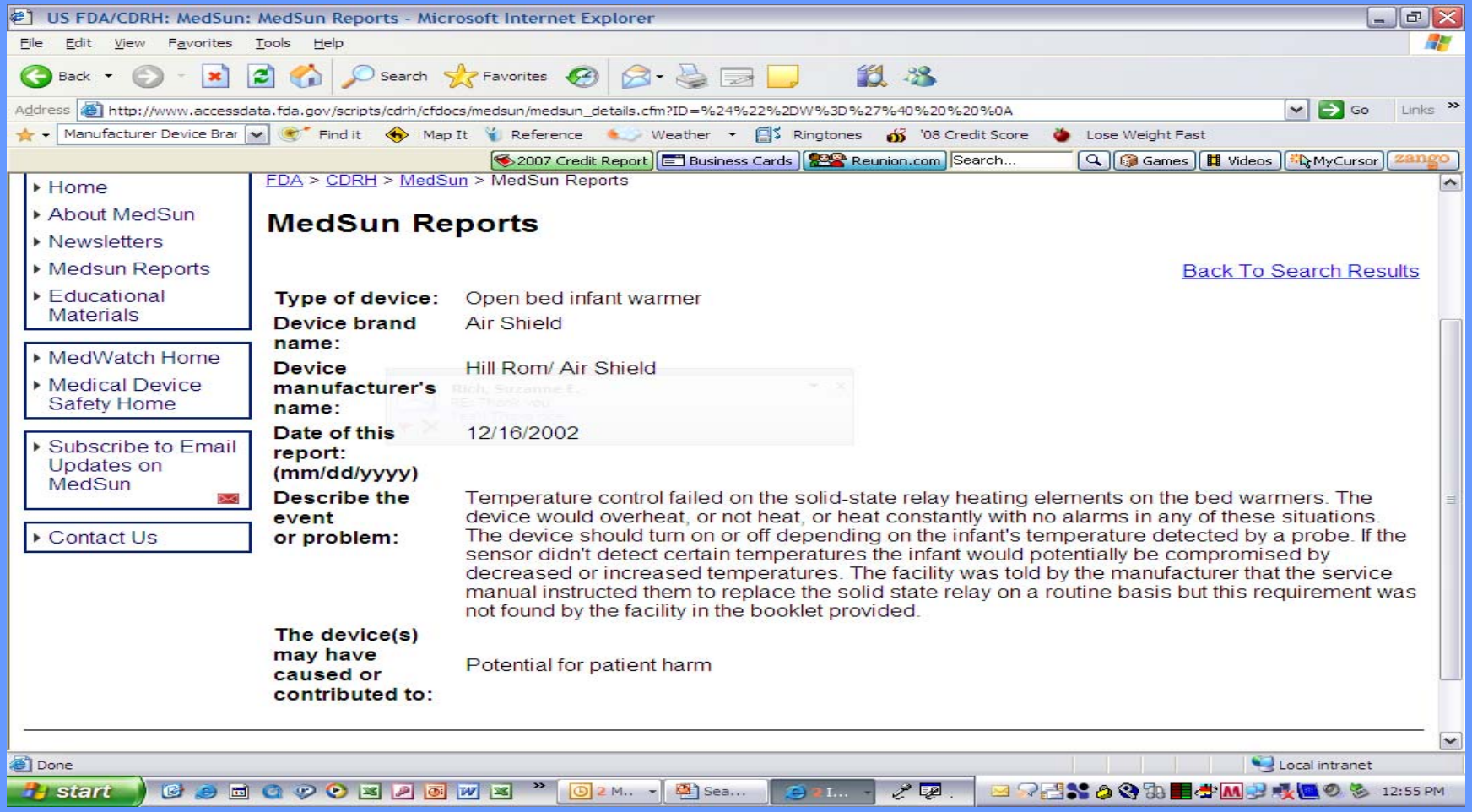
Searching the MedSun Database from the MedSun Online Newsletter

- Double click on ‘Reports’ - found on the left hand side of the home page screen
- There are two methods of searching available to you:
  - Simple Search
  - Advanced Search

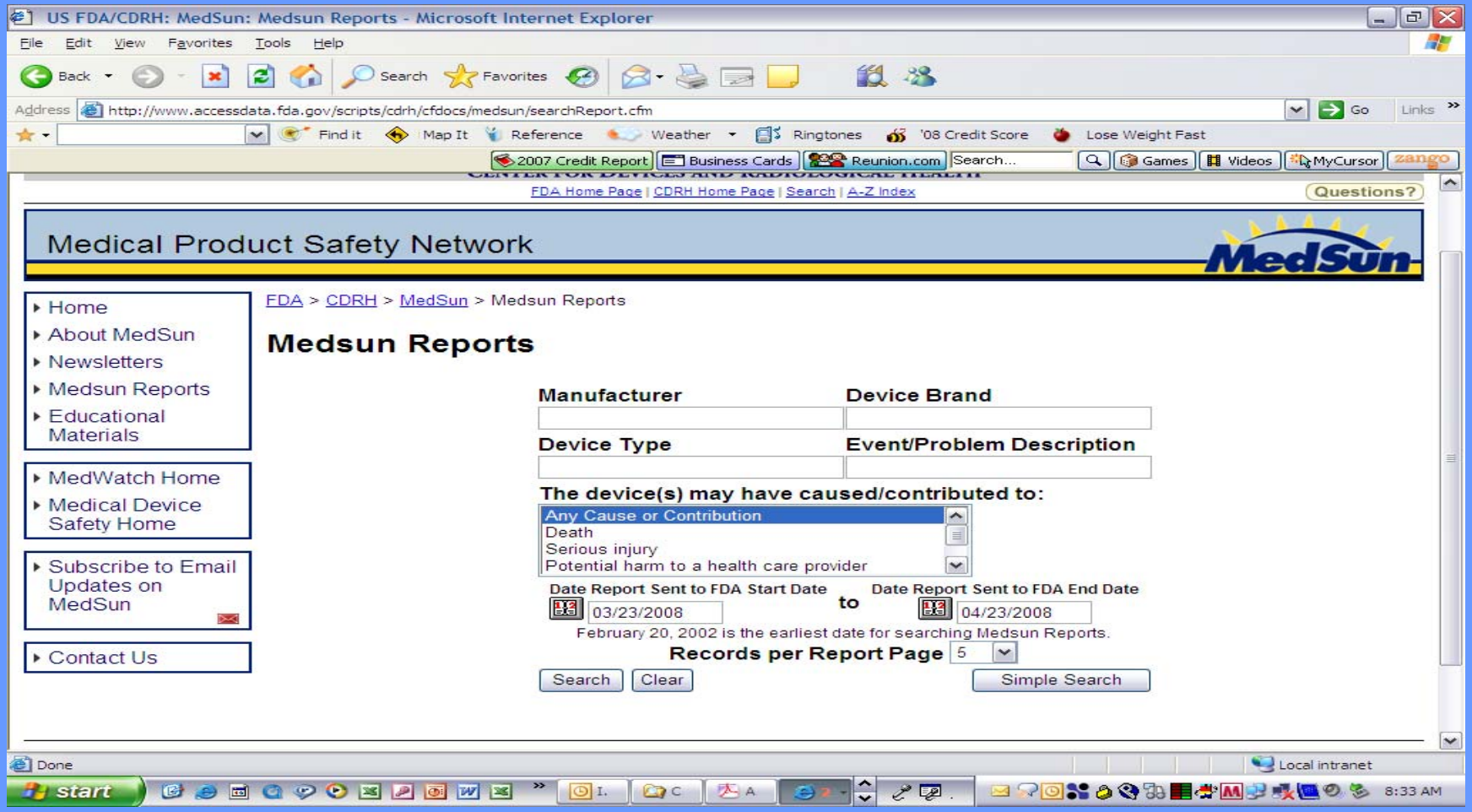
MedSun Simple Search



MedSun Simple Search Results



MedSun Advanced Search



MedSun Advanced Search Features

- Selecting the advanced search feature allows you to search by inputting one or more criteria in the text boxes denoted below:

Manufacturer	Device Brand
Event/Problem Description	Device Type

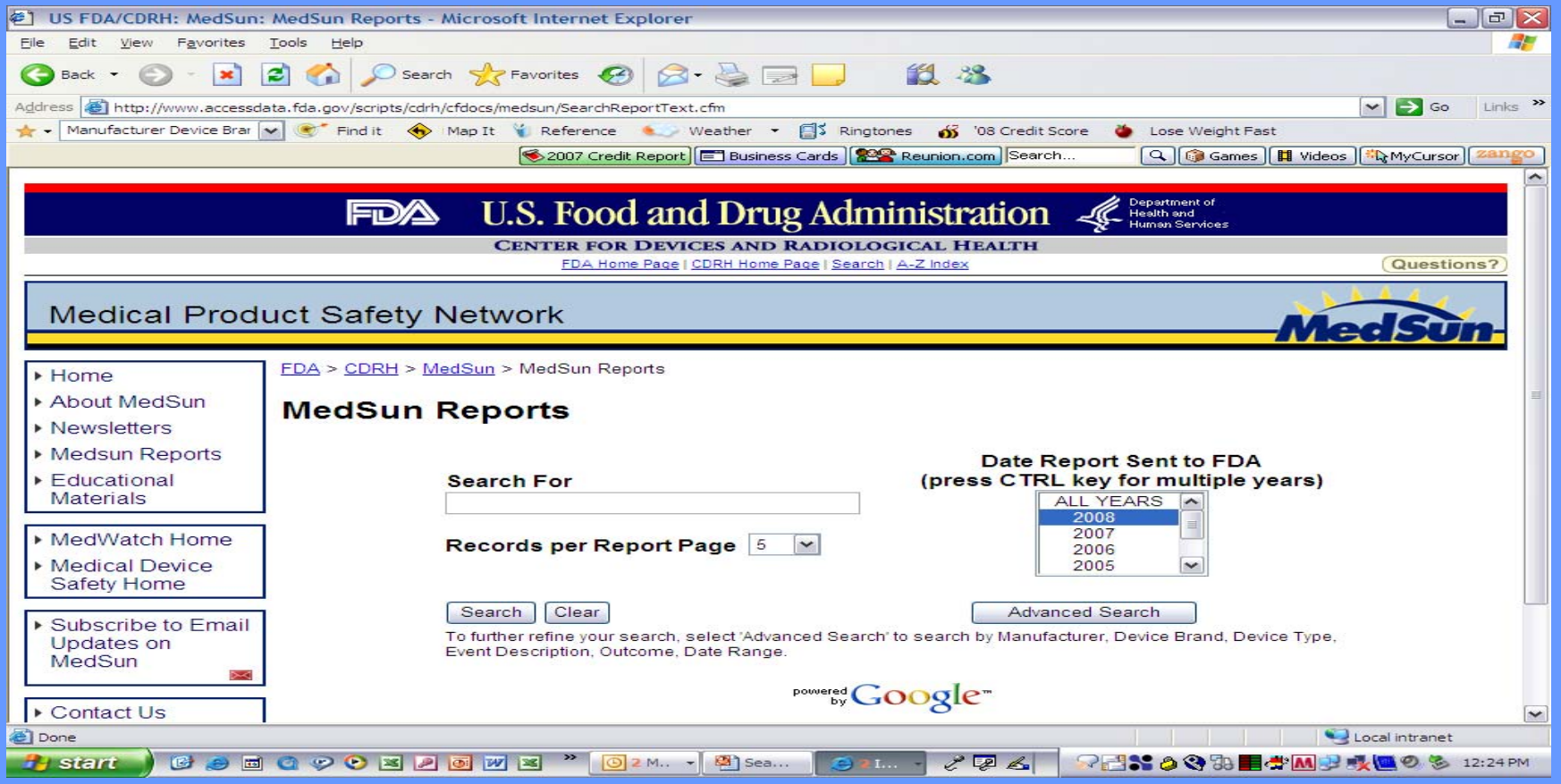
  - The device(s) may have caused/contributed to:
    - Any cause or contribution
    - Death
    - Serious injury
    - Potential harm to health care provider
    - Minor injury to the patient or health care provider
    - Potential for patient harm

MedSun Advanced Search Features
(cont'd)

- Note: February 20, 2002 is the earliest date for searching MedSun Reports
  - Input date range with a beginning date
  - Input date range with an end date or the current date as necessary
  - Select records to be displayed per page
    - 5
    - 10
    - 25
    - 50

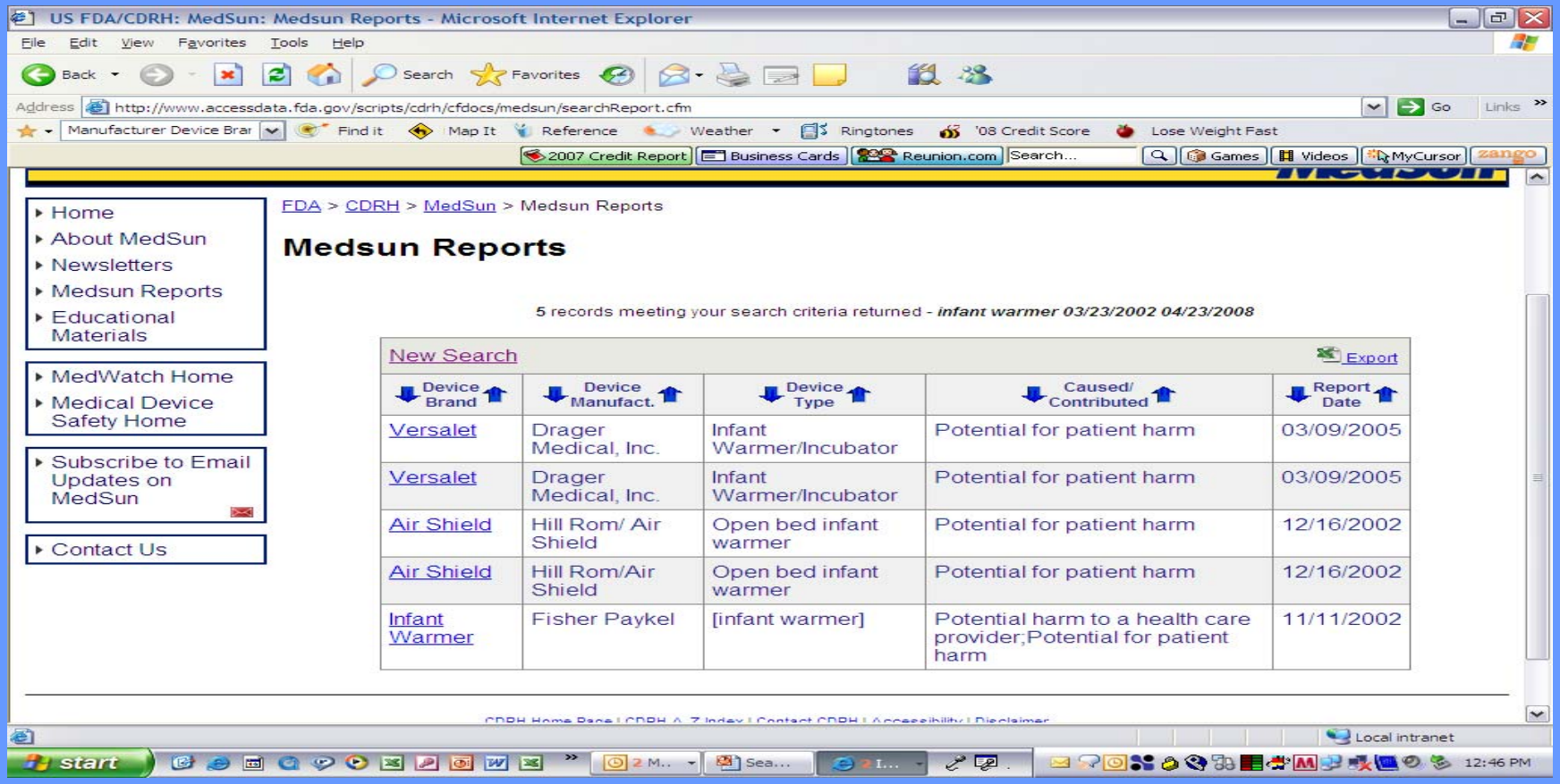
MedSun Pre-Programmed Reports: MedSun Search Results Presented in a Table

(based on your selected search criteria)



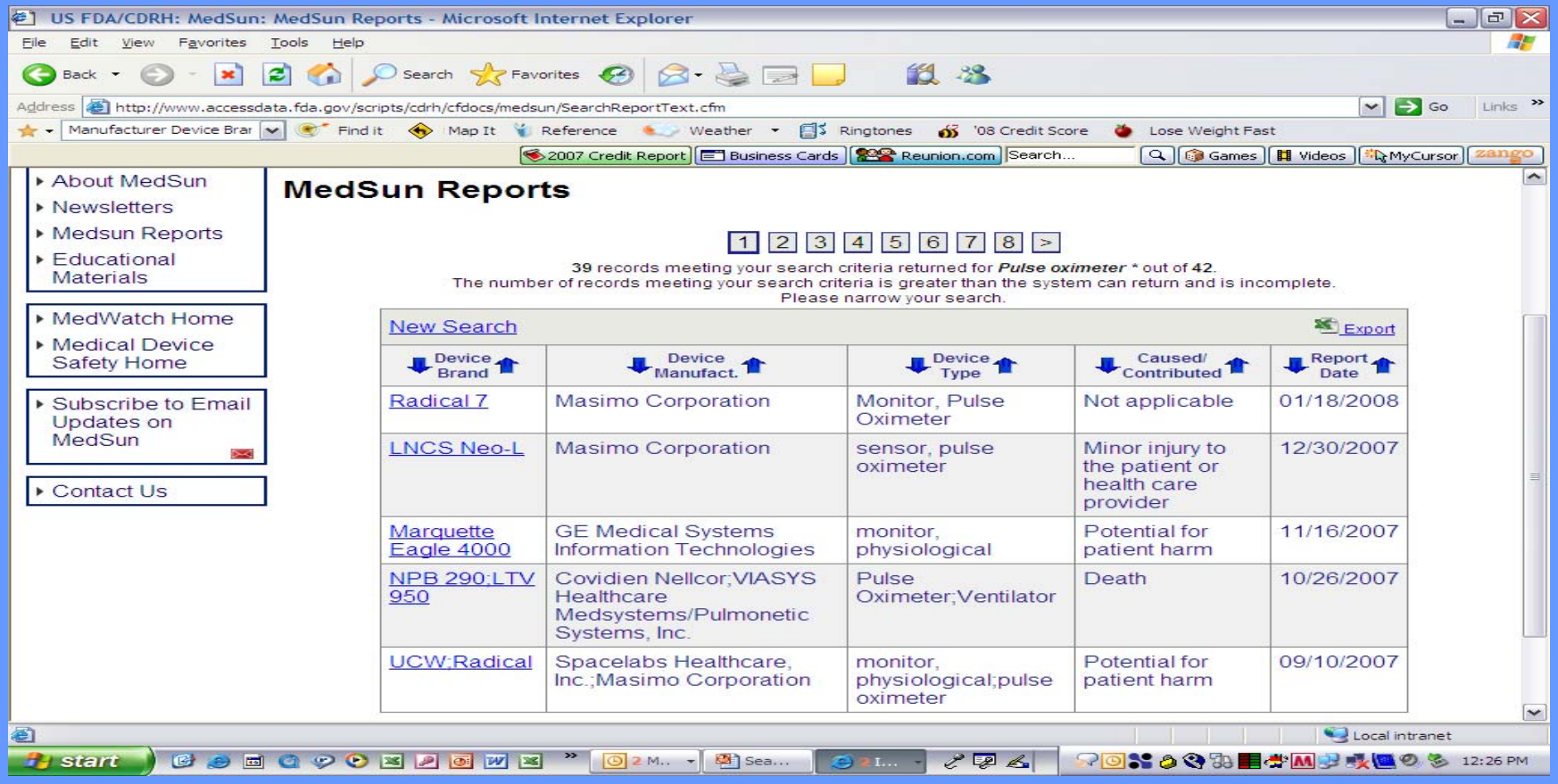
MedSun Advanced Search Results

(based on your selected search criteria)



MedSun Advanced Search Results

(note that large sets of results will be displayed on multiple pages)



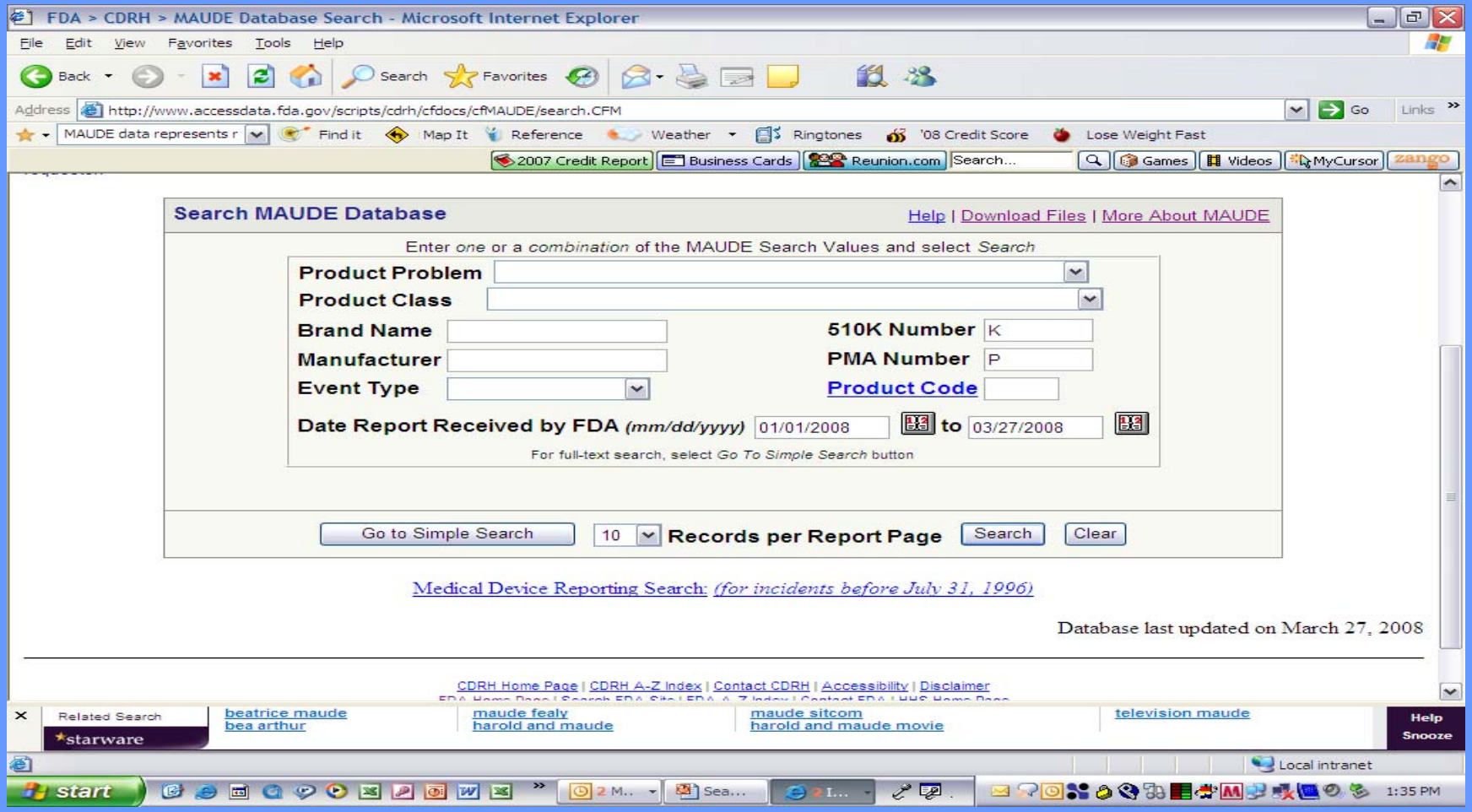
Public Maude

- 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.
- The on-line search allows you to search CDRH 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.

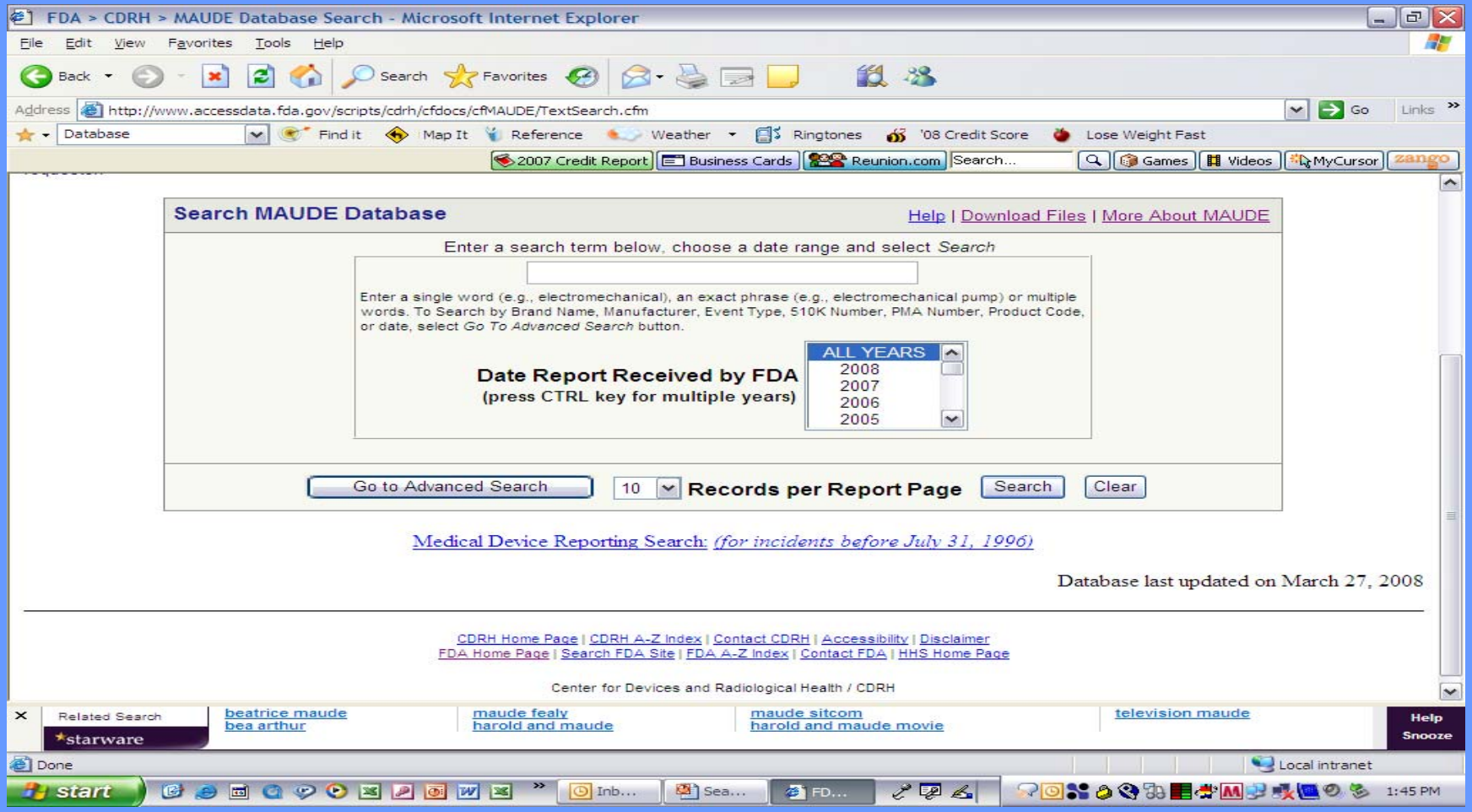
Search Criteria for Public Maude

- Input your search criteria into any of the following fields. Most have drop down dialog boxes to assist you with selecting search criteria:
  - Product Problem
  - Product Class
  - Brand Name
  - 510k Number
  - Manufacturer
  - PMA Number
  - Event Type
  - **Product Code ***a three-letter descriptor used to identify device type**
  - Date range
  - Number of records to be displayed per page
    - 5-10-25-50-100-500

Public Maude

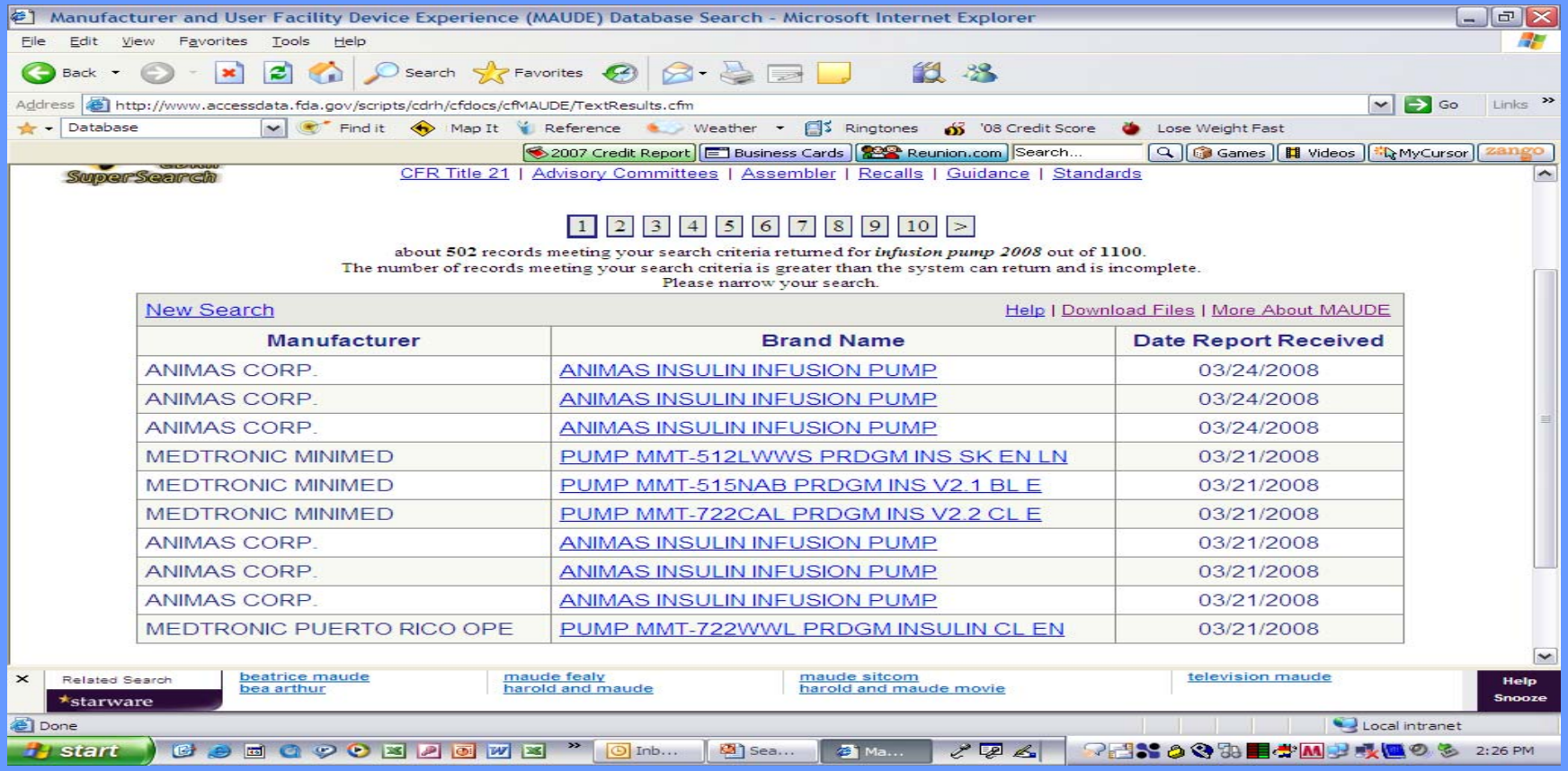


Maude Database Simple Search



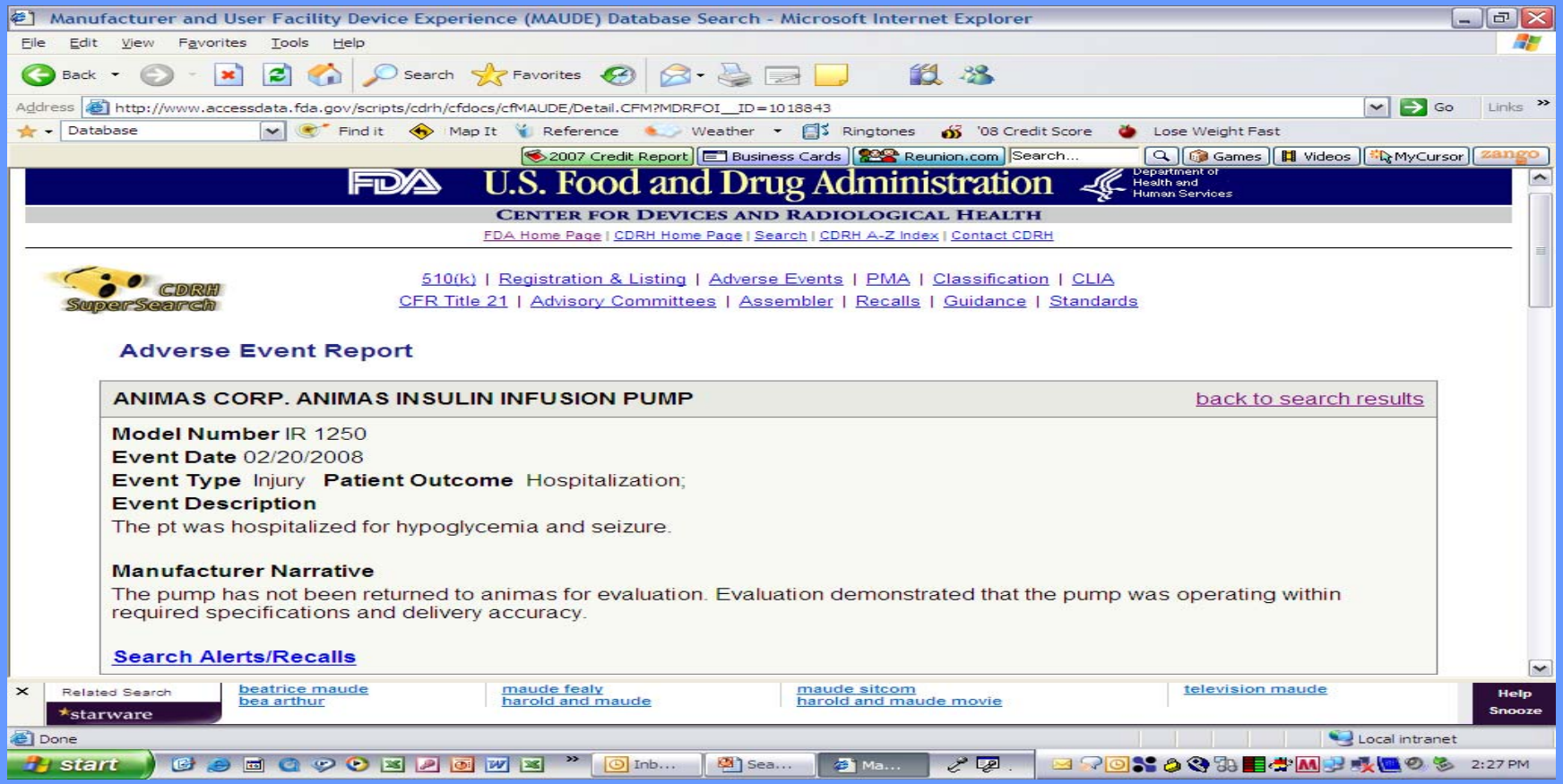
MAUDE Simple Search Results

(note the underlined text in search results table)

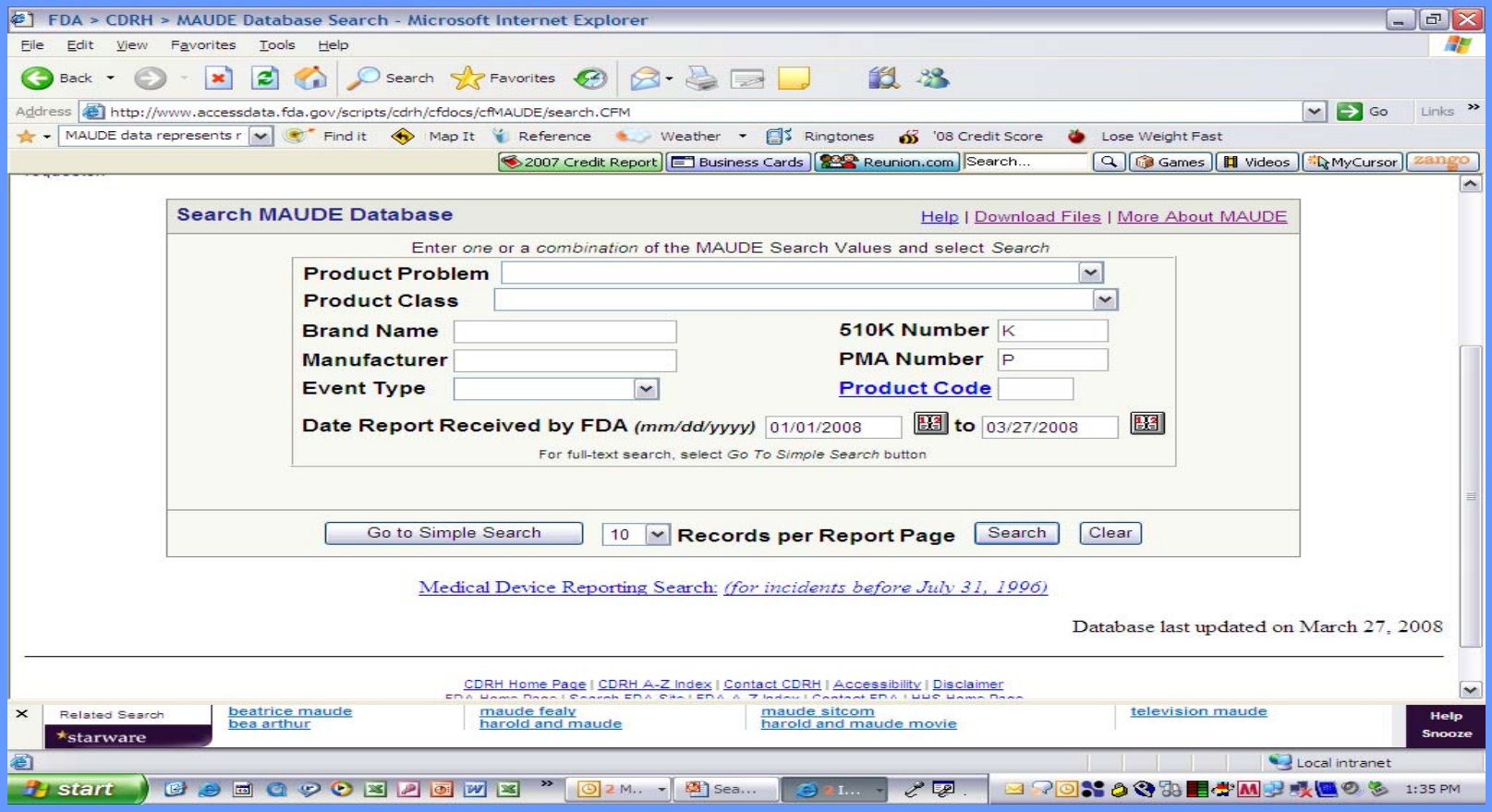


Display Individual MAUDE Reports from Simple Search Results

(click on underlined text in search results table)



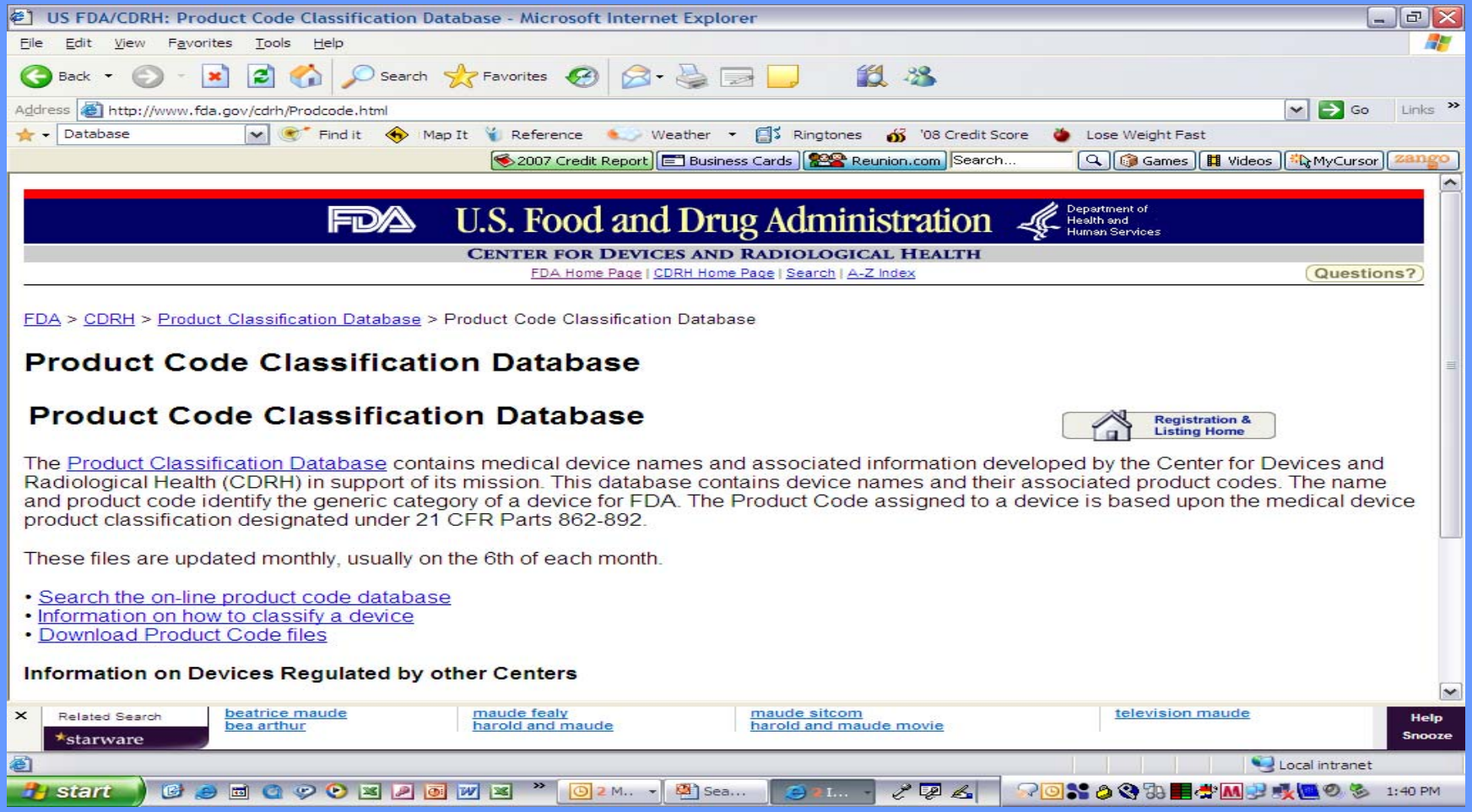
MAUDE Advanced Search



What Product Code to Enter?

- You can query the Product Code database if you are unclear on which product code to enter into your search criteria
- You will be redirected to the Product Code database
- Or you can search the Product Code database via this link:
  - http://www.fda.gov/cdrh/Productcode.html
- Enter in search terms to utilize this database

Product Code Database



Neonatal Product Codes

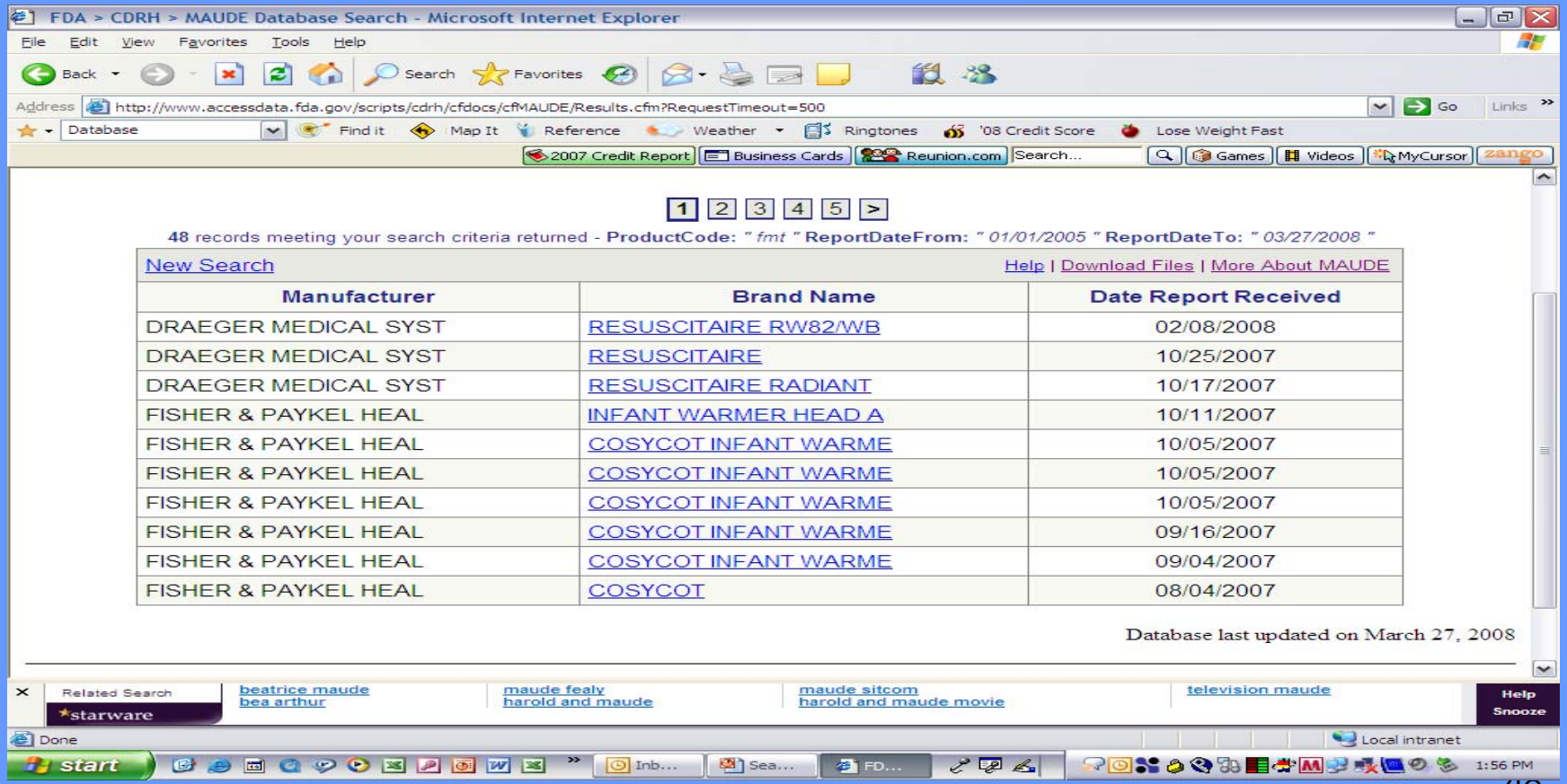
- FMT - warmer, infant radiant
- FMZ - incubator, neonatal
- FPL – incubator, neonatal transport
- LBI – phototherapy unit, neonatal
- FOS – catheter, umbilical artery
- HIQ – electrode, fetal scalp
- FLS- monitor, apnea, facility-use
- FOK – pad, neonatal eye

Pediatric Product Codes

- **FFH – collector, urine, pediatric, for indwelling catheter**
- **FMS – bed, pediatric open-hospital**
- **FNC – tent, pediatric aerosol**
- **GBN – catheter, pediatric, general & plastic surgery**
- **KKO – ring, teething, fluid-filled**
- **OBT – plate, bone, growth control, pediatric, epiphysiodesis**
- **OFP – anesthesia breathing circuit kit (adult & pediatric)**

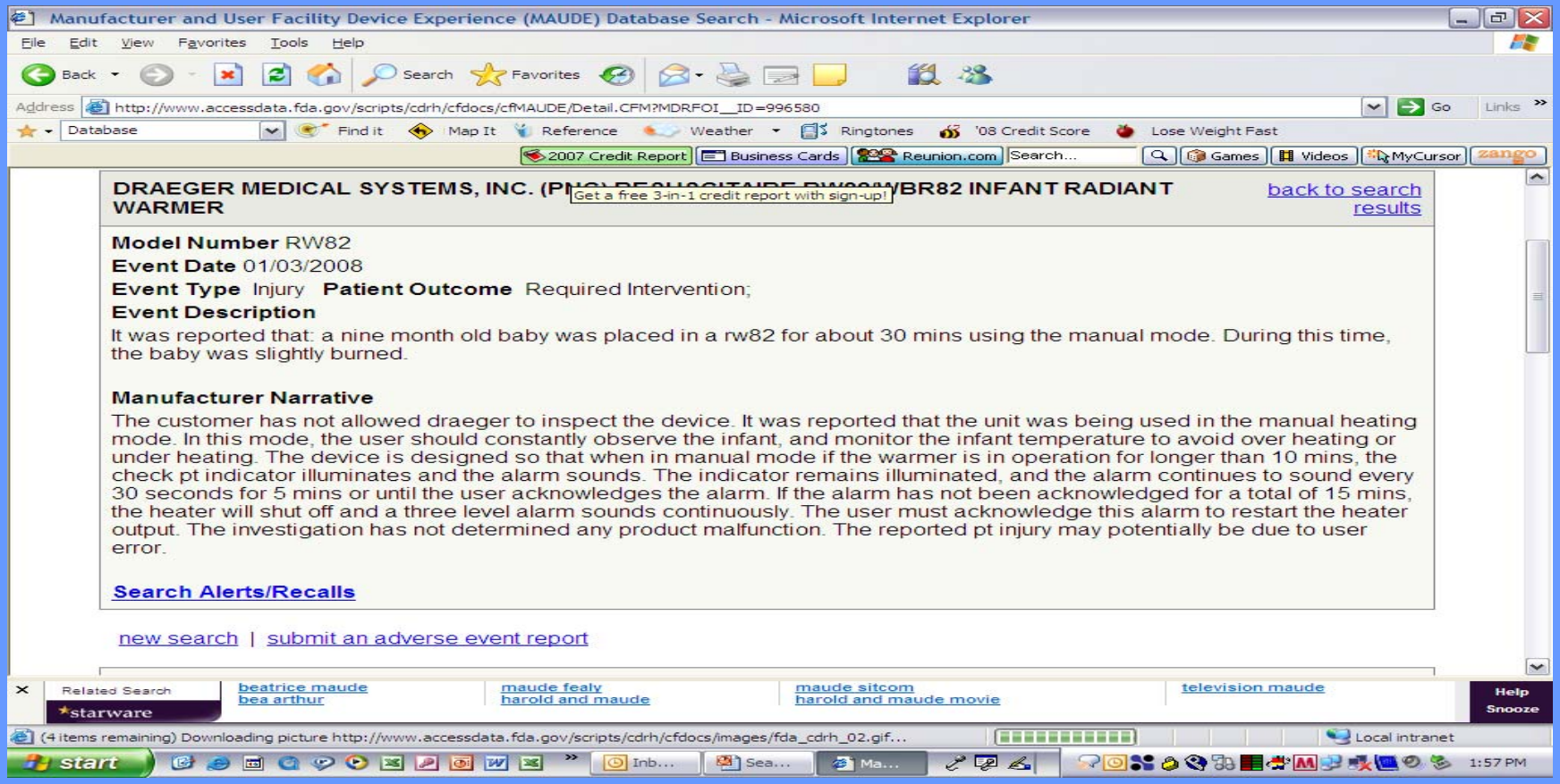
MAUDE Advanced Search Results

(note the underlined text in search results table)

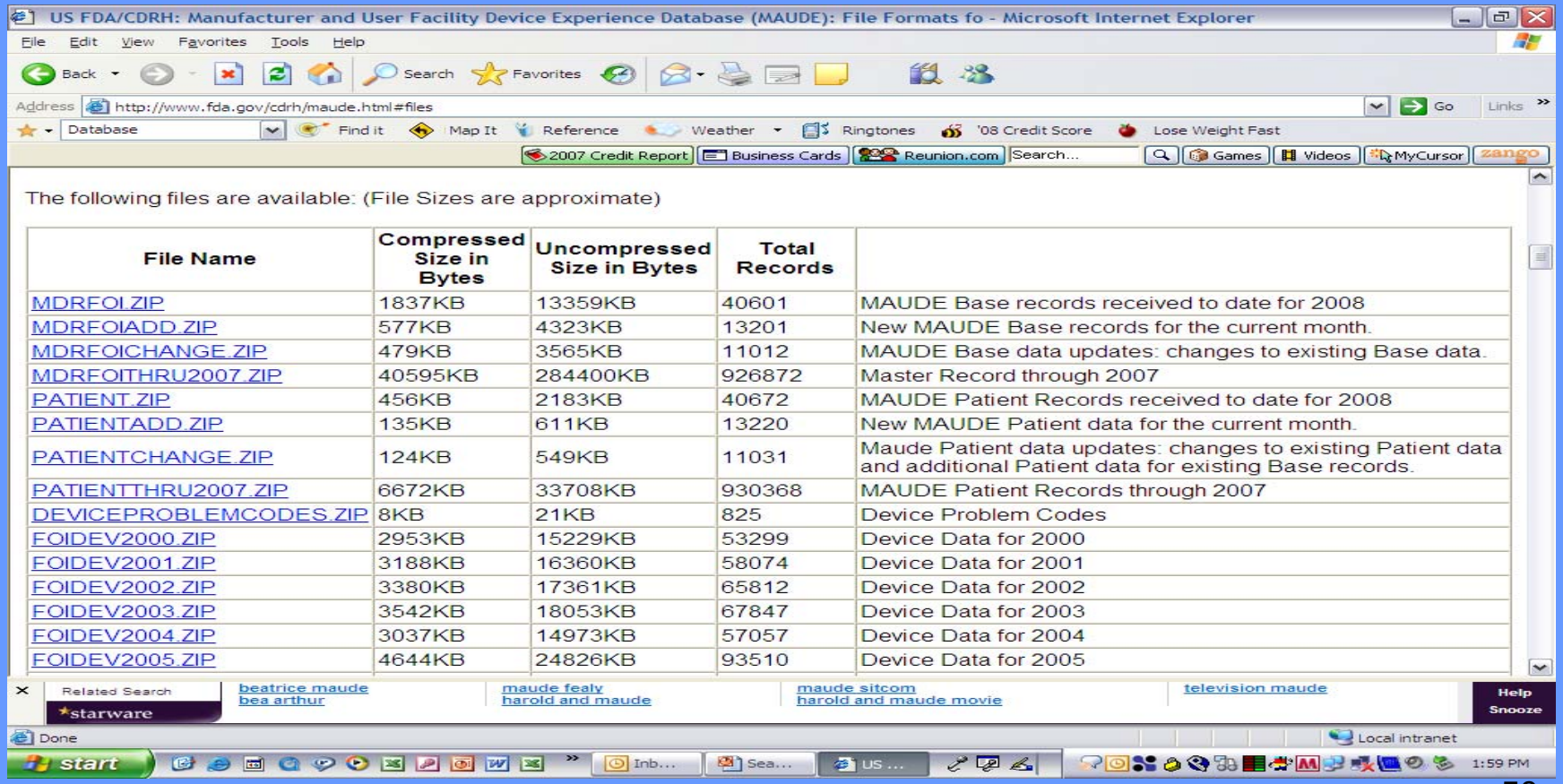


Display Individual MAUDE Reports from Advanced Search Results

(click on underlined text in search results table)



Availability of Maude Adverse Events for Downloading onto your Computer



The following files are available: (File Sizes are approximate)

File Name	Compressed Size in Bytes	Uncompressed Size in Bytes	Total Records	
MDRFOI.ZIP	1837KB	13359KB	40601	MAUDE Base records received to date for 2008
MDRFOIADD.ZIP	577KB	4323KB	13201	New MAUDE Base records for the current month.
MDRFOICHANGE.ZIP	479KB	3565KB	11012	MAUDE Base data updates: changes to existing Base data.
MDRFOITHRU2007.ZIP	40595KB	284400KB	926872	Master Record through 2007
PATIENT.ZIP	456KB	2183KB	40672	MAUDE Patient Records received to date for 2008
PATIENTADD.ZIP	135KB	611KB	13220	New MAUDE Patient data for the current month.
PATIENTCHANGE.ZIP	124KB	549KB	11031	Maude Patient data updates: changes to existing Patient data and additional Patient data for existing Base records.
PATIENTTHRU2007.ZIP	6672KB	33708KB	930368	MAUDE Patient Records through 2007
DEVICEPROBLEMCODES.ZIP	8KB	21KB	825	Device Problem Codes
FOIDEV2000.ZIP	2953KB	15229KB	53299	Device Data for 2000
FOIDEV2001.ZIP	3188KB	16360KB	58074	Device Data for 2001
FOIDEV2002.ZIP	3380KB	17361KB	65812	Device Data for 2002
FOIDEV2003.ZIP	3542KB	18053KB	67847	Device Data for 2003
FOIDEV2004.ZIP	3037KB	14973KB	57057	Device Data for 2004
FOIDEV2005.ZIP	4644KB	24826KB	93510	Device Data for 2005

Summary

- Both public databases (MedSun and MAUDE) are accessed via the Internet Explorer
- All information contained in these databases falls under the Freedom of Information Act
- Results can be printed to your local printer