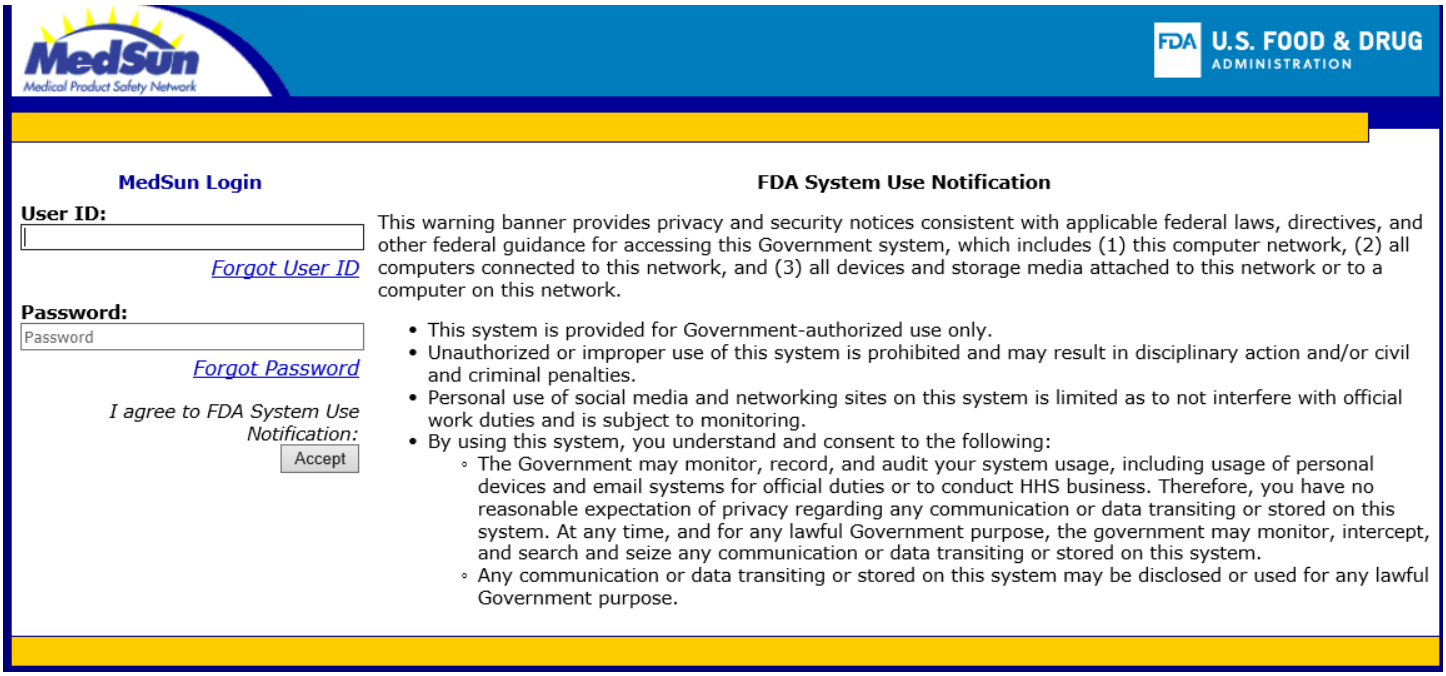
MedSun Database Screenshots

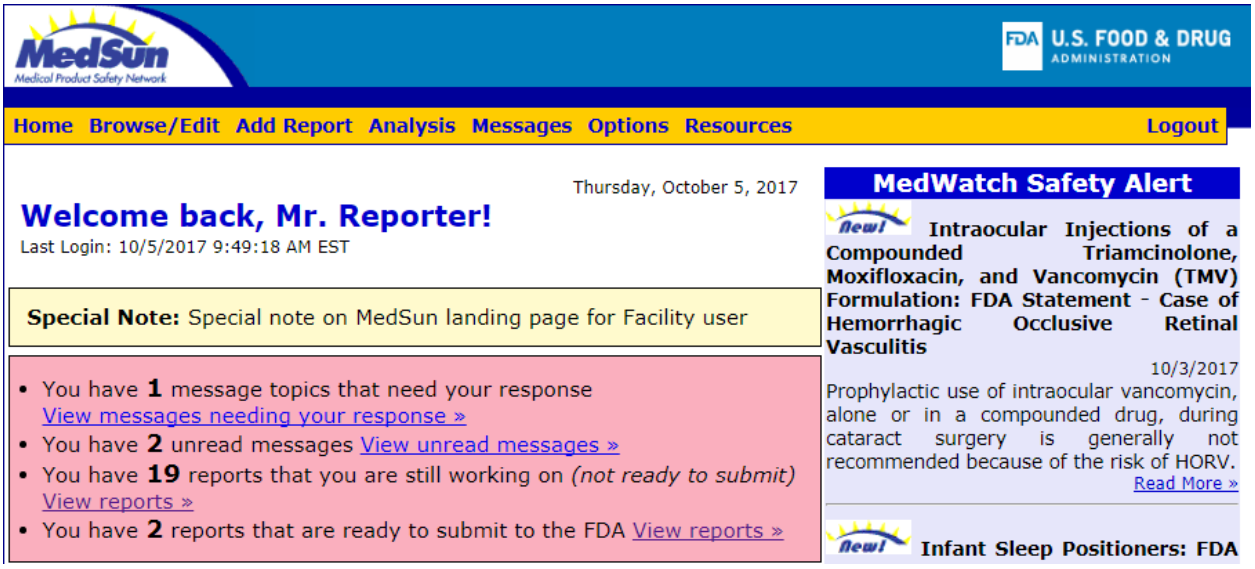
April 2020

Contents

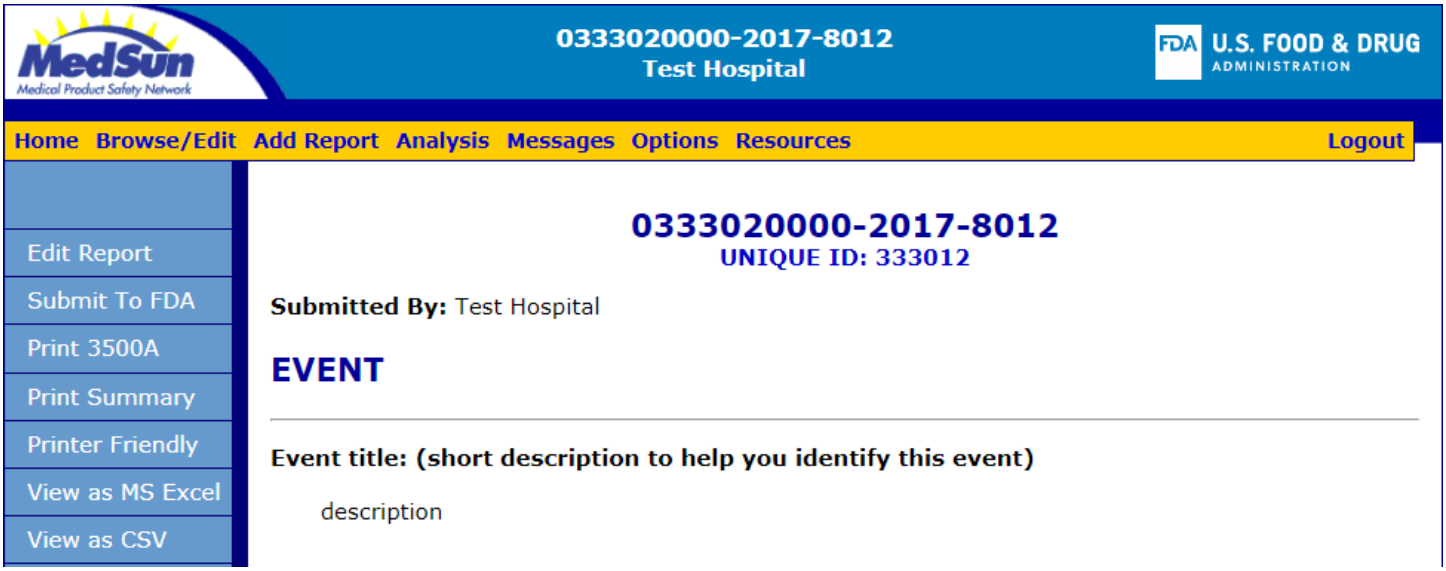
MedSun Login Page



Home Page



"Browse/Edit" Page with Browse dropdown options


MedSun
Medical Product Safety Network
0333020000-2017-8012
Test Hospital
FDA U.S. FOOD & DRUG ADMINISTRATION
Home Browse/Edit Add Report Analysis Messages Options Resources Logout
Edit Report
Submit To FDA
Print 3500A
Print Summary
Printer Friendly
View as MS Excel
View as CSV
0333020000-2017-8012
UNIQUE ID: 333012
Submitted By: Test Hospital
EVENT
Event title: (short description to help you identify this event)
description

- Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.
- Paperwork Reduction Act Statement

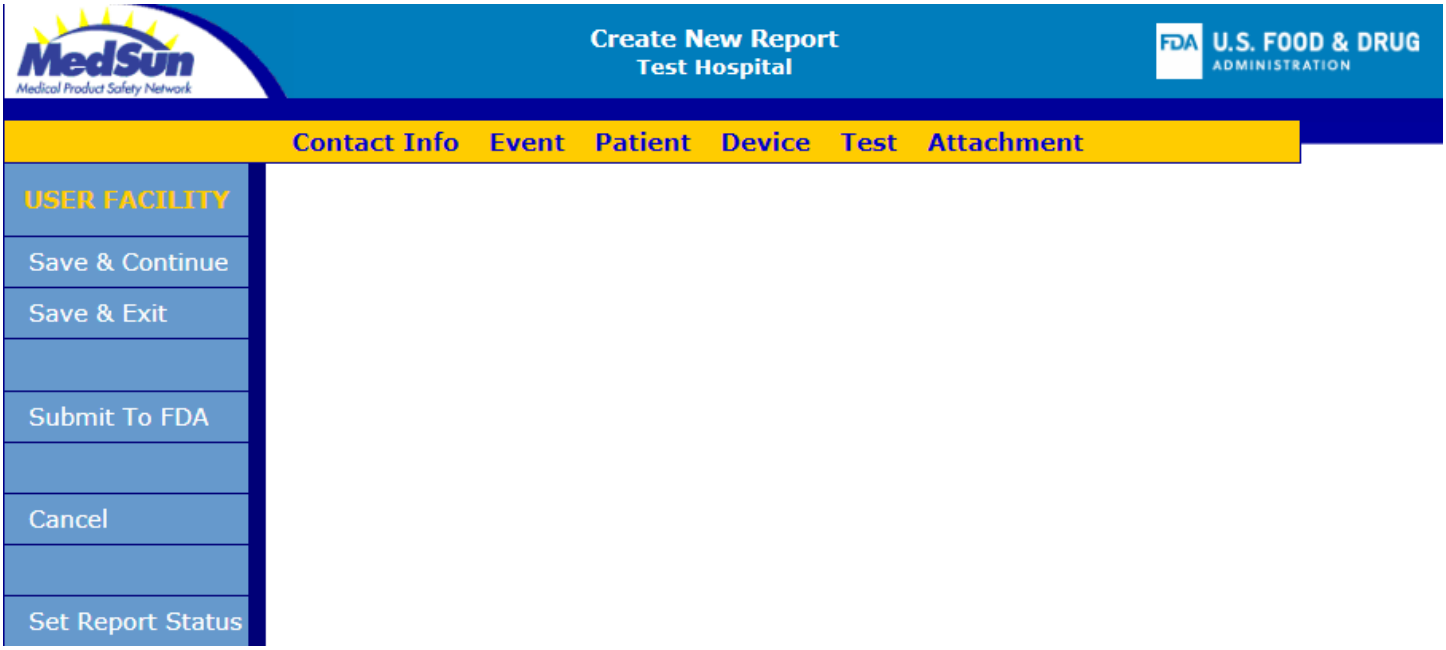
  Public reporting burden for this collection of information is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

  Department of Health and Human Services
  Food and Drug Administration
  Office of the Chief Information Officer (HFA-250)
  5600 Fishers Lane
  Rockville, Maryland 20857

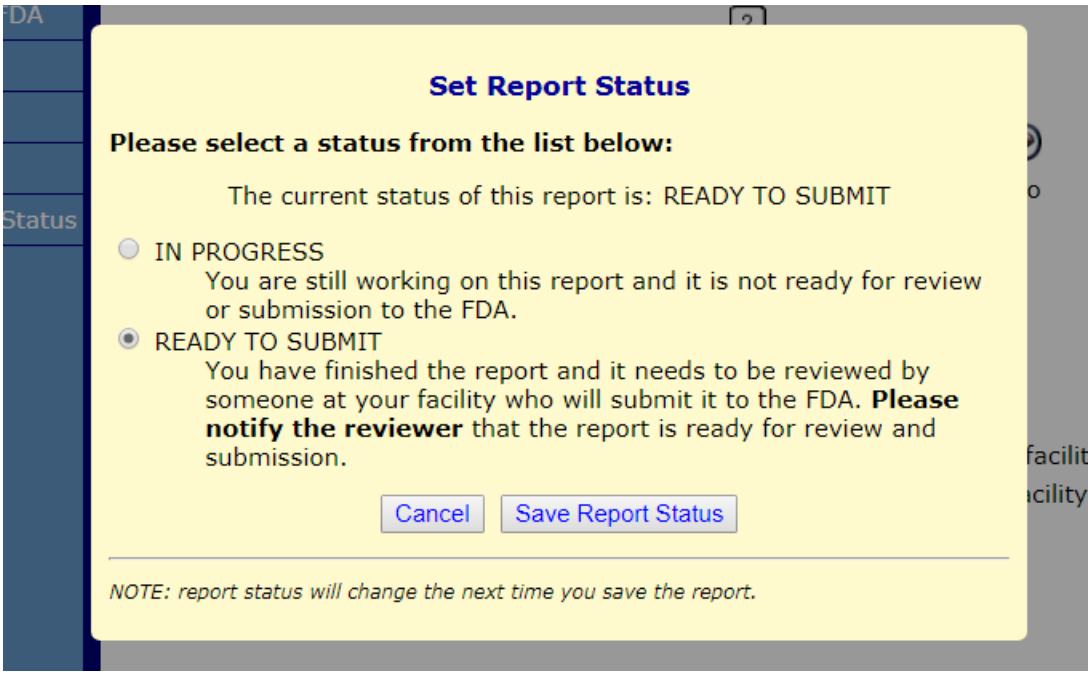
  An agency may not conduct or sponsor, and a person is not allowed to respond to, a collection of information unless it displays a currently valid OMB control number.
- **FORM FDA 3670(05/17)**
  OMB Number: 0910-0471
  Expiration date: 6/30/2020

Enter the report form

Edit Report Navigation



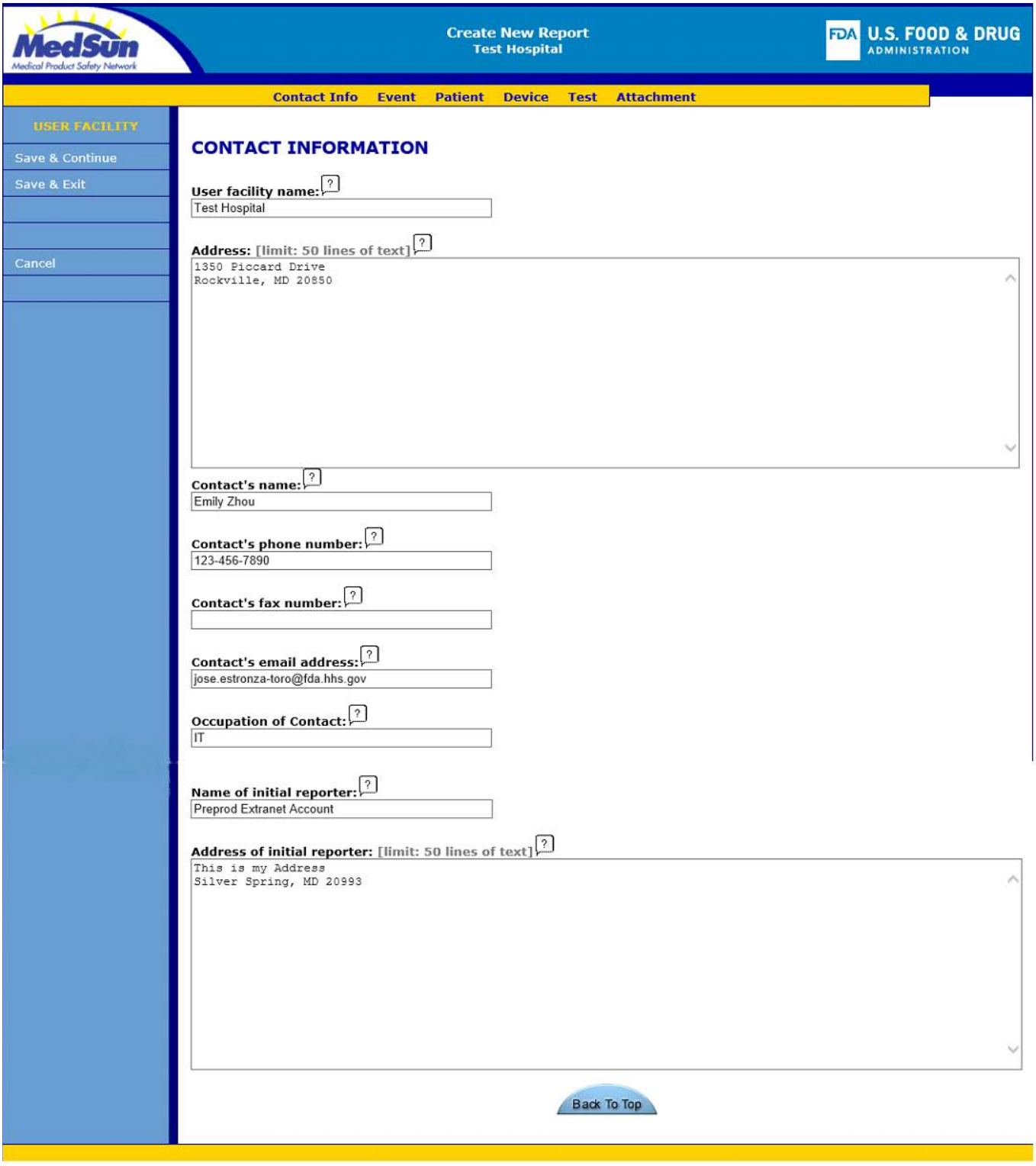
Edit Set Report Status

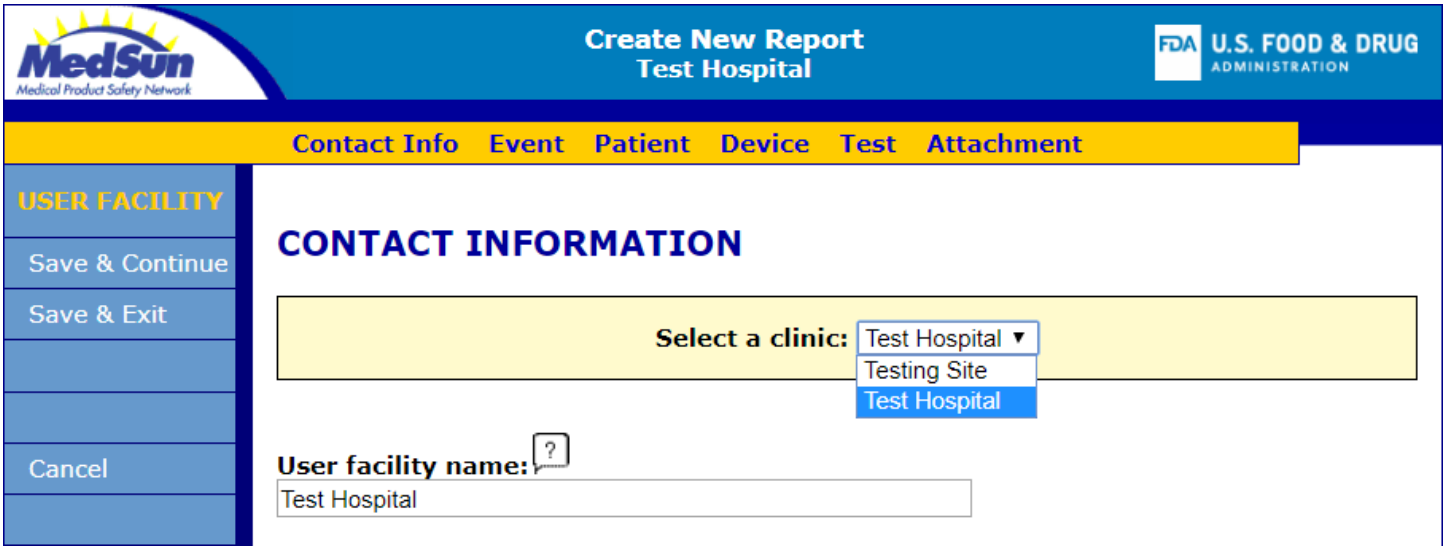


Edit Report Submit

Contact Info

Edit/Add Report “Contact Infor”




MedSun
Medical Product Safety Network
Create New Report
Test Hospital
FDA U.S. FOOD & DRUG ADMINISTRATION
Contact Info
Event
Patient
Device
Test
Attachment
USER FACILITY
Save & Continue
Save & Exit
Cancel
CONTACT INFORMATION
Select a clinic:
Test Hospital
Testing Site
Test Hospital
User facility name:
Test Hospital

Event

Edit/Add Report “Event”

EVENT INFORMATION

Event title: (short description to help you identify this event)

When did the event happen? (mm/dd/yyyy)

How many days ago did you first become aware of the event?
- ○ less than or equal to 10 days ago
- ○ more than 10 days ago

Date of this report: (mm/dd/yyyy)
12/19/2017

Where did this event occur?
- ○ Hospital
- ○ Nursing home
- ○ Outpatient diagnostic facility
- ○ Laboratory not within a hospital
- ○ Not known
- ○ Other
- ○ Home
- ○ Outpatient treatment facility
- ○ Ambulatory surgical facility
- ○ Physician's office
- ○ Not applicable

The device(s) may have caused or contributed to: (Check all that apply)
- ☐ Death
- ☐ Serious injury
- ☐ Potential harm to a health care provider [Indicates voluntary report]
- ☐ Minor injury to the patient or health care provider [Indicates voluntary report]
- ☐ Potential for patient harm [Indicates voluntary report]
- ☐ Not known
- ☐ Not applicable

Was there a problem with the device (such as a defect, malfunction, break, etc)?
- ○ Yes
- ○ Not known
- ○ No
- ○ Not applicable

Was someone directly "operating" the device at the time of the event?
- ○ Yes
- ○ Not known
- ○ No
- ○ Not Applicable

Were there other devices being used on the patient at the time of the event that may have caused or contributed to the event? [limit: 50 lines of text]

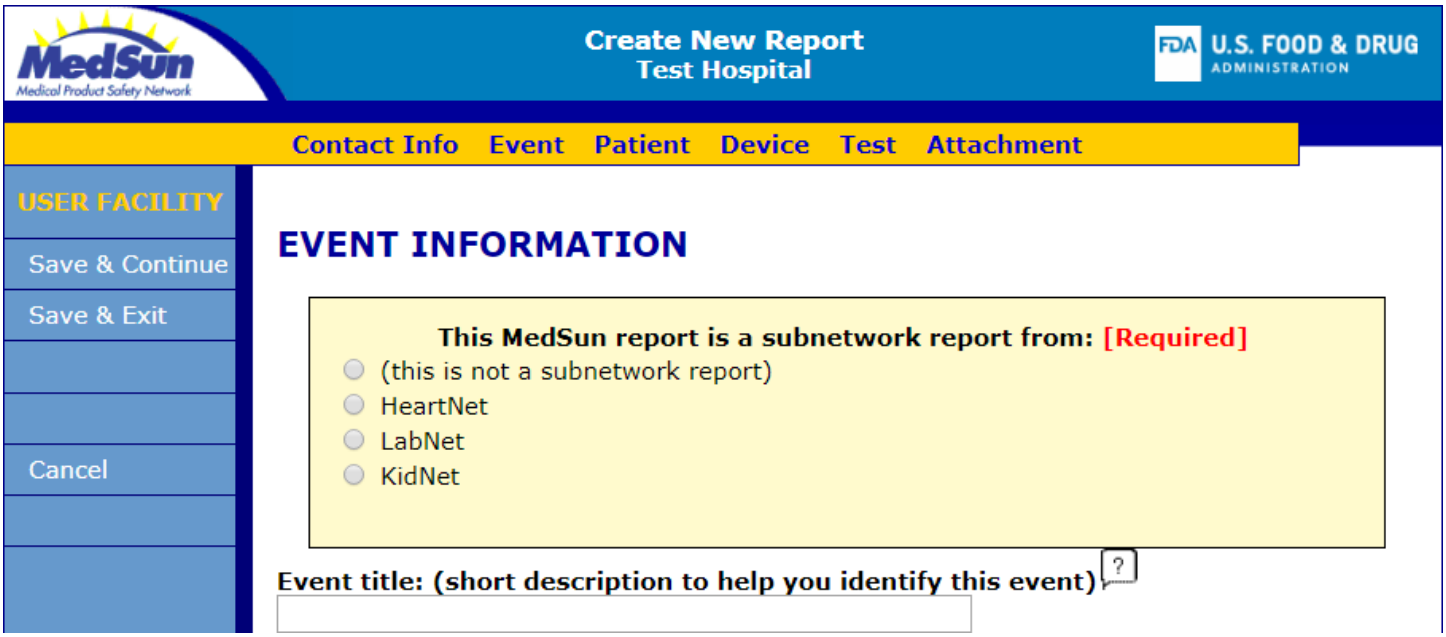
Were there other therapies being used on the patient at the time of the event that may have caused or contributed to the event? (Check all that apply)
- ☐ Cardiac Drugs
- ☐ Dialysis
- ☐ Long-Term Antibiotics
- ☐ Other
- ☐ Not known
- ☐ Chemotherapy
- ☐ Immunotherapy
- ☐ Prenatal medication
- ☐ No other therapies
- ☐ Not applicable

Describe the event or problem. Please provide as much detail as possible. [limit: 50 lines of text]

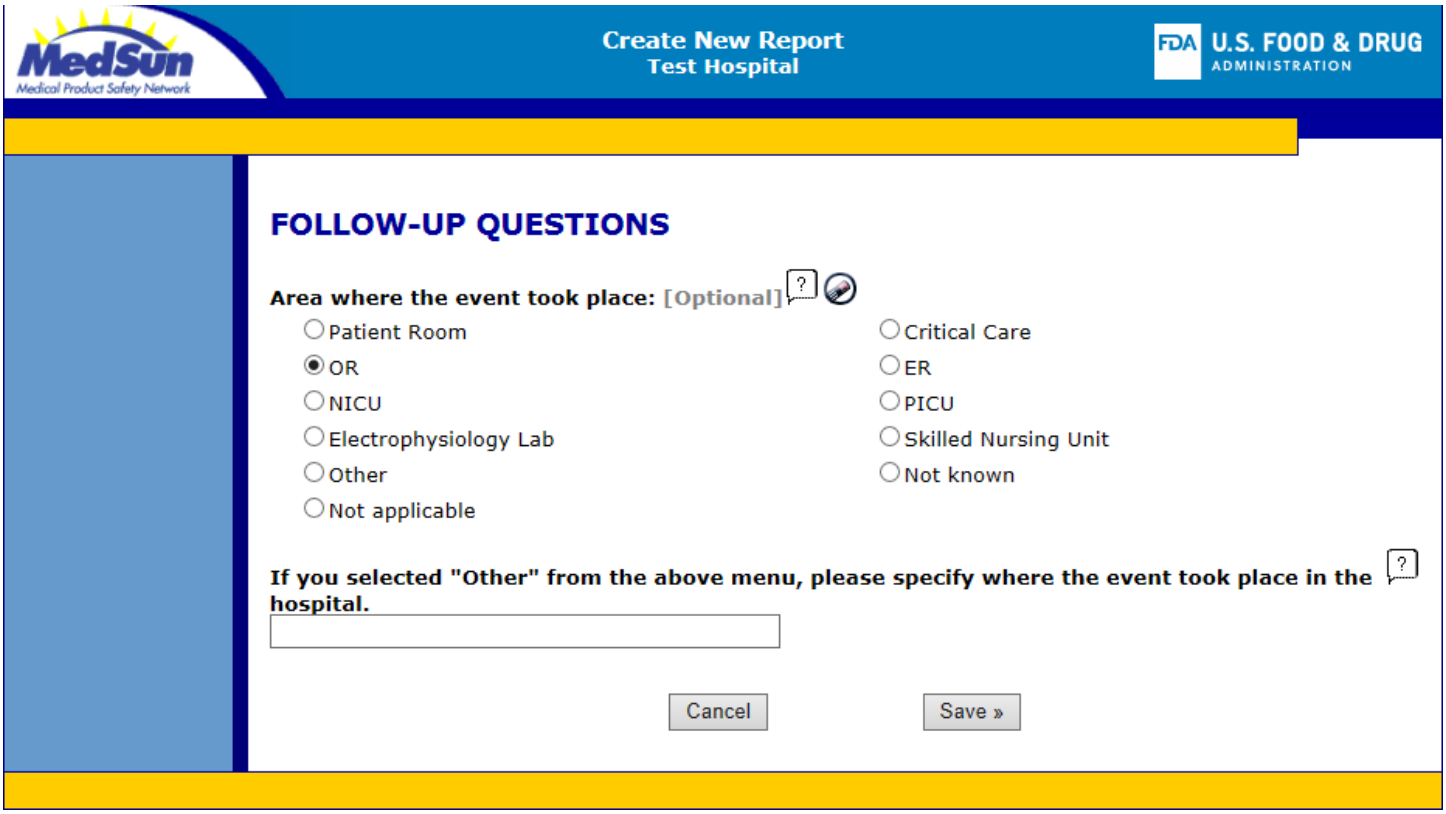
What was the original intended procedure?

Back To Top

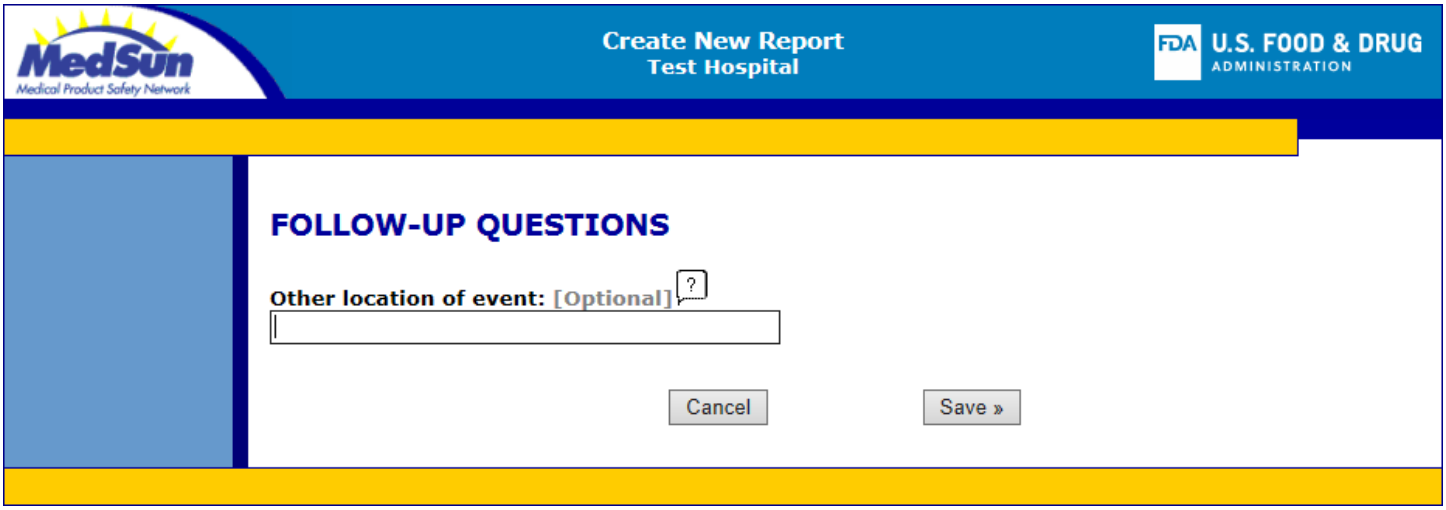
Add Report Event with Network Pick (used by few sites)



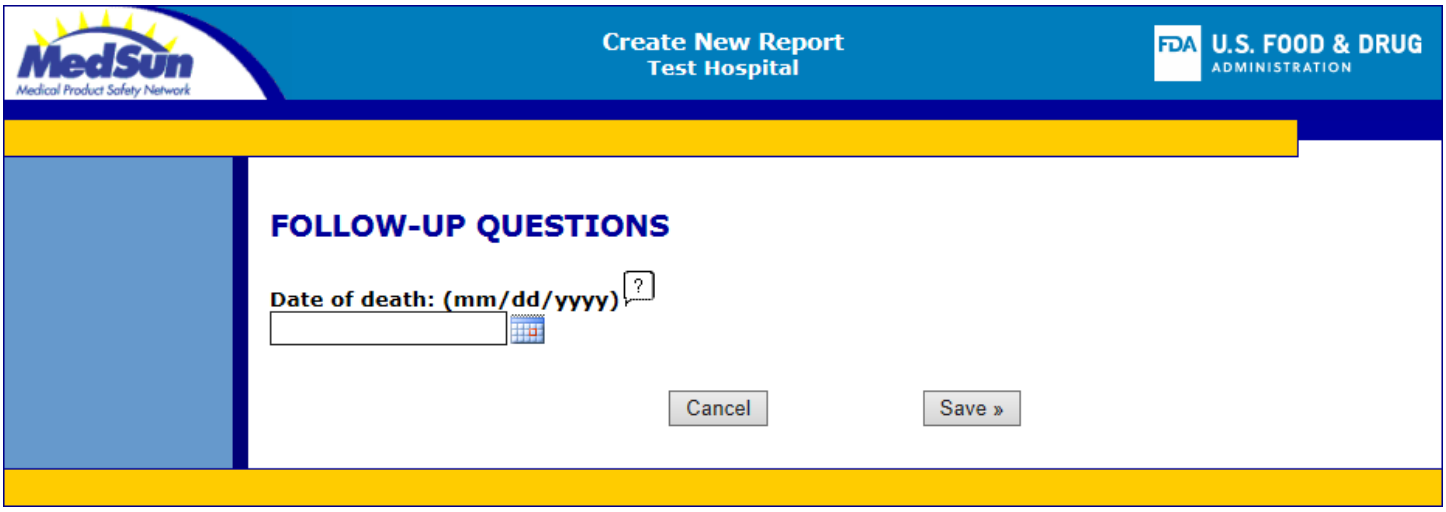
Add Report Event Follow Up Where2



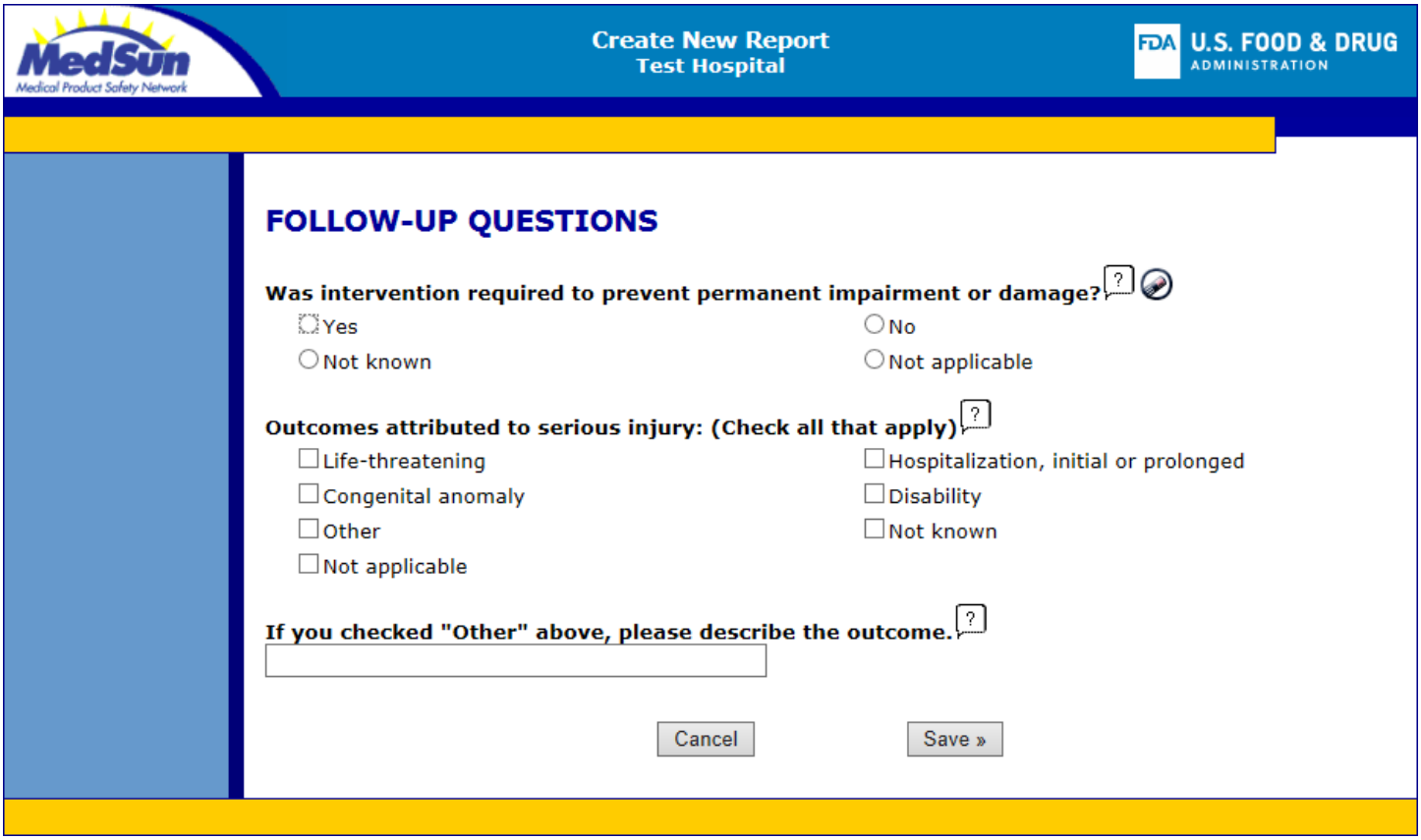
Add Report Event Follow Up Other Location



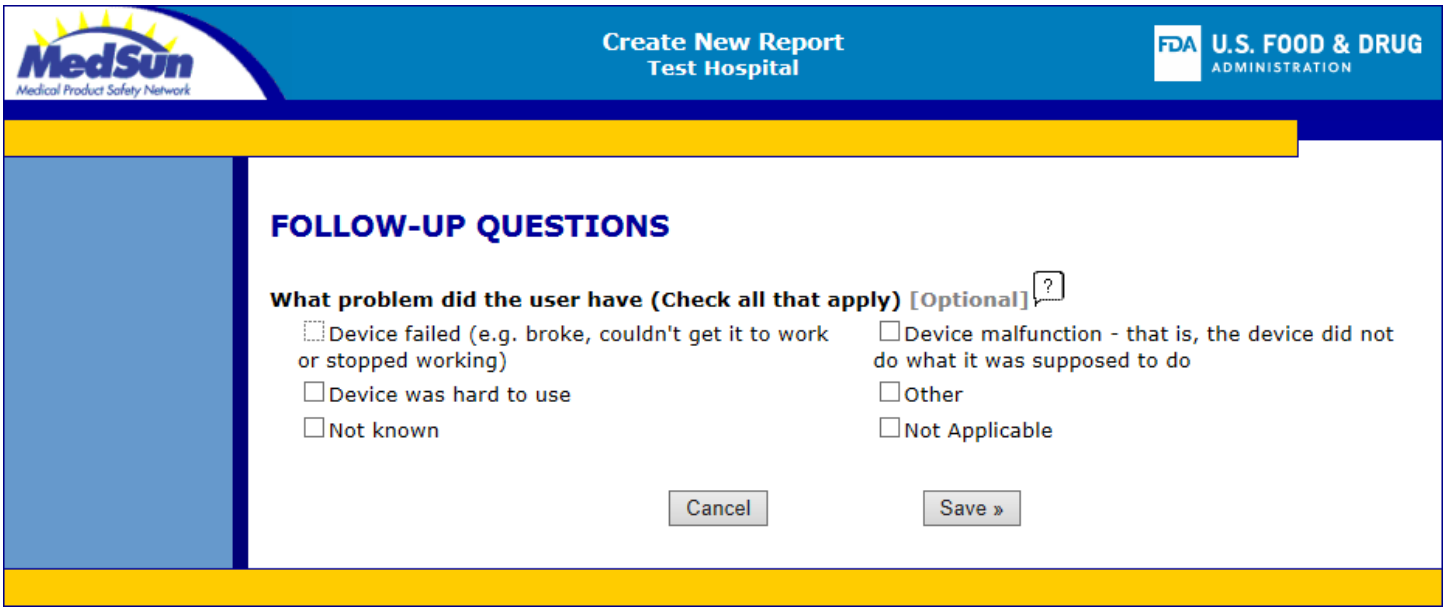
Add Report Event Follow Up Death



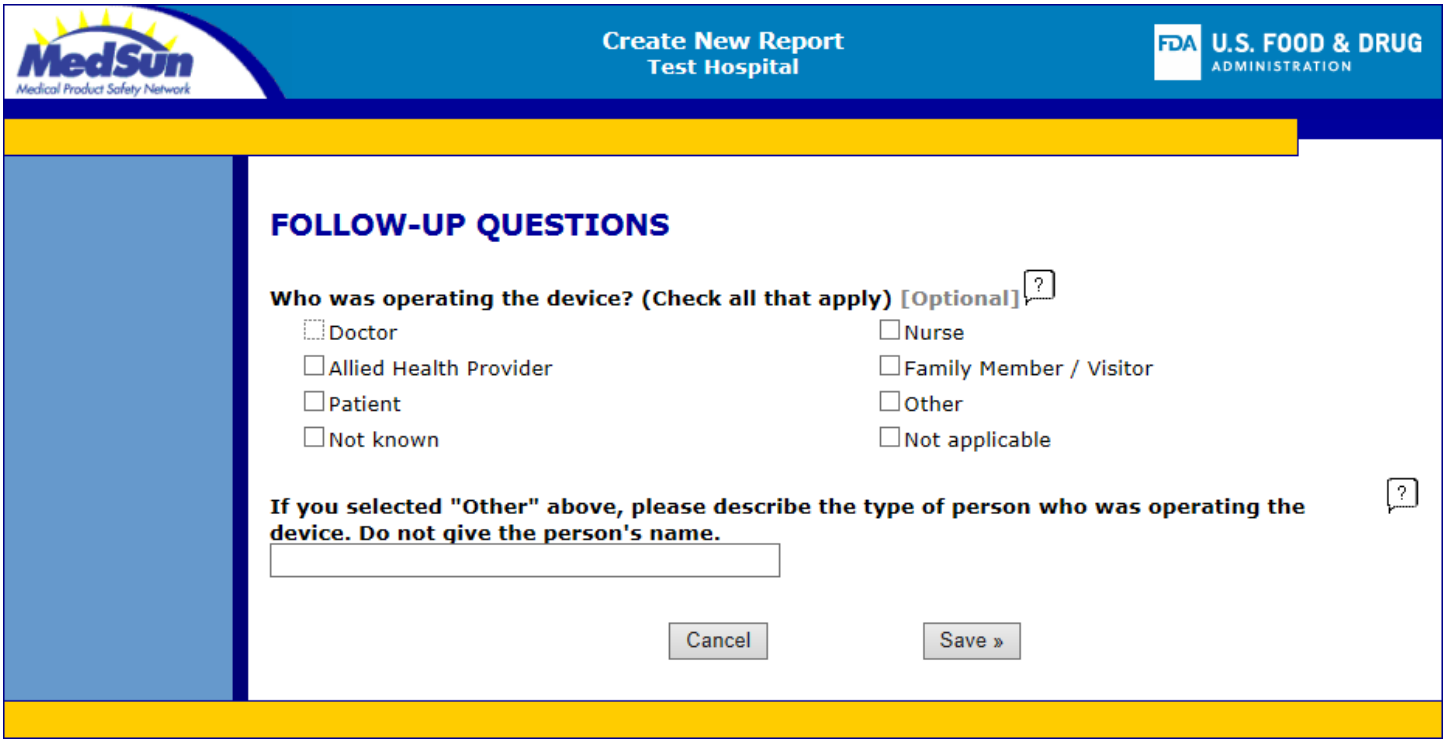
Add Report Event Follow Up Serious Injury



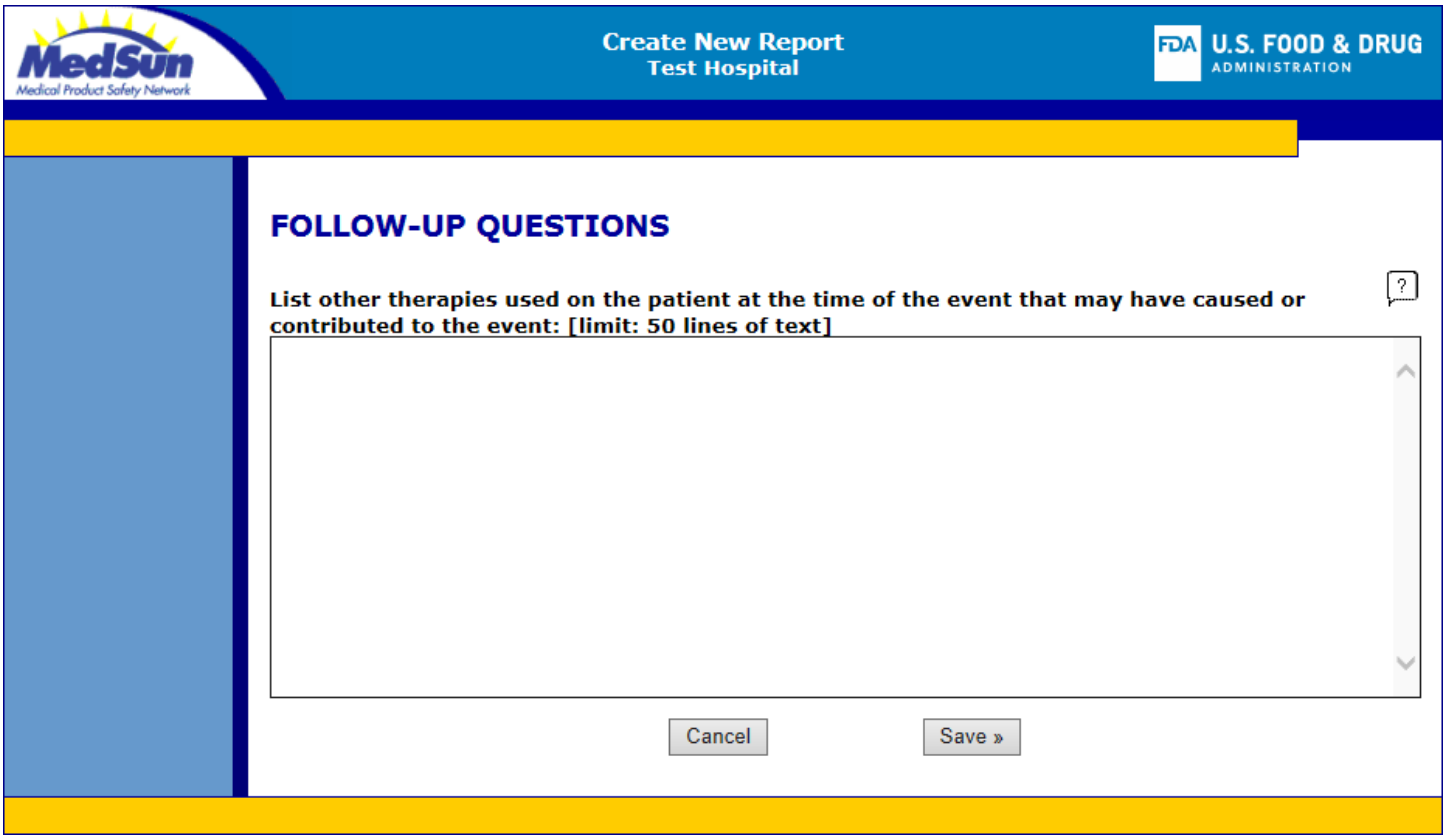
Add Report Event Follow Up Device Problem



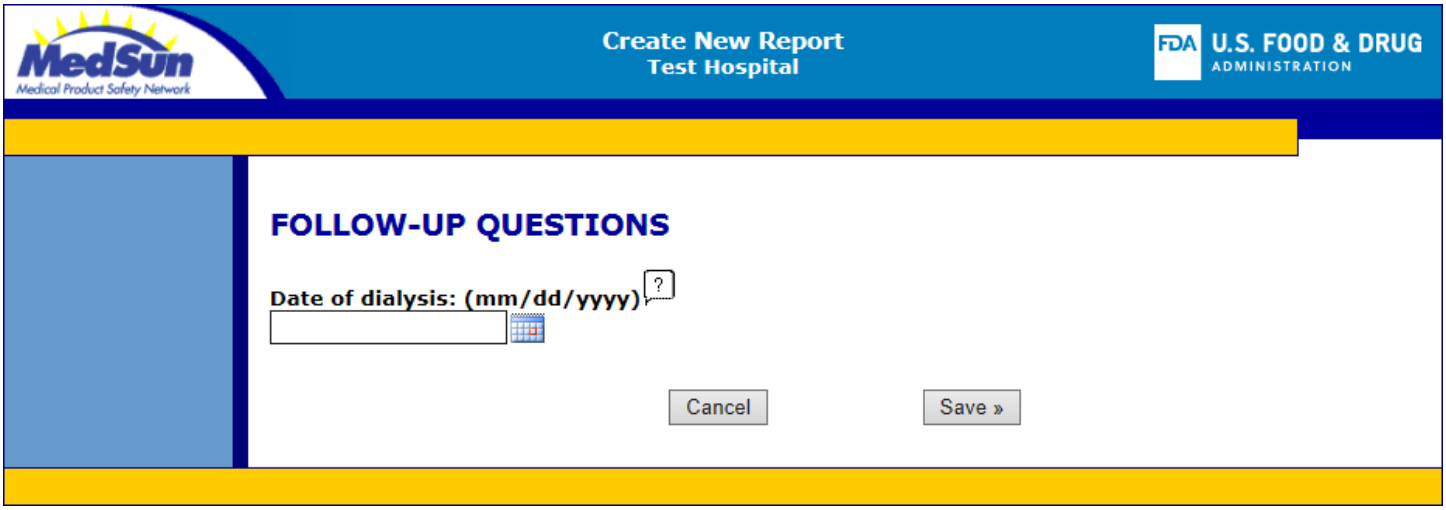
Add Report Event Follow Up Operating Device



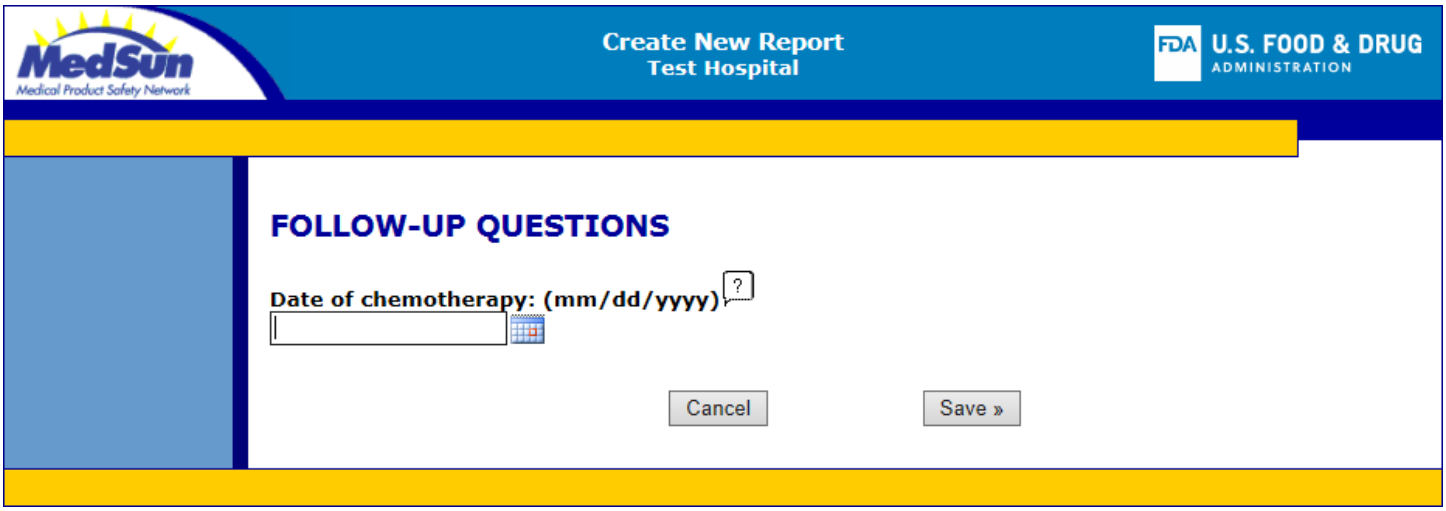
Add Report Event Follow Up Other Therapies



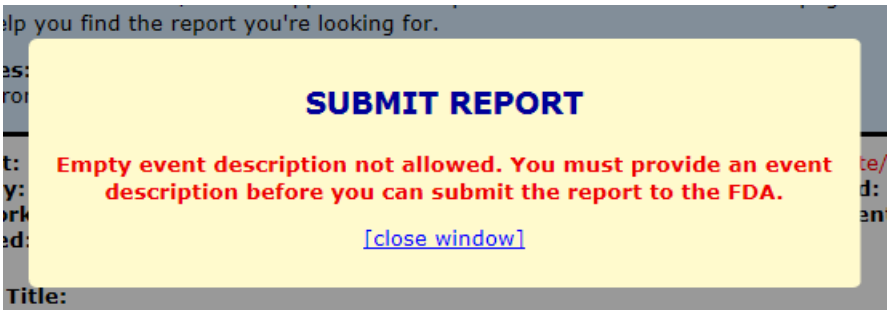
Add Report Event Follow Up Dialysis



Add Report Event Follow Up Chemotherapy



Edit Report Submit Missing Event



Edit/Add Report “Patient List” Empty

Edit/Add Report “Patient List” Empty

PATIENT INFORMATION

Patient identifier: (DO NOT USE the patient's name, initials, social security number, date of birth, medical record number or other personal identifiers)

(Please limit your response to 8 characters)

Patient's age at time of event:

Years / Months / Weeks / Days / DOB / Do not know / Not applicable

Patient's gender

- ○ Male
- ○ Female
- ○ Not known
- ○ Not applicable

Patient's weight: (select unit or "do not know")

Kilograms / Pounds / Grams / Ounces / Do not know / Not applicable

Patient's race and ethnic background (check all that apply): [Optional]

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Unknown
- ☐ Not applicable

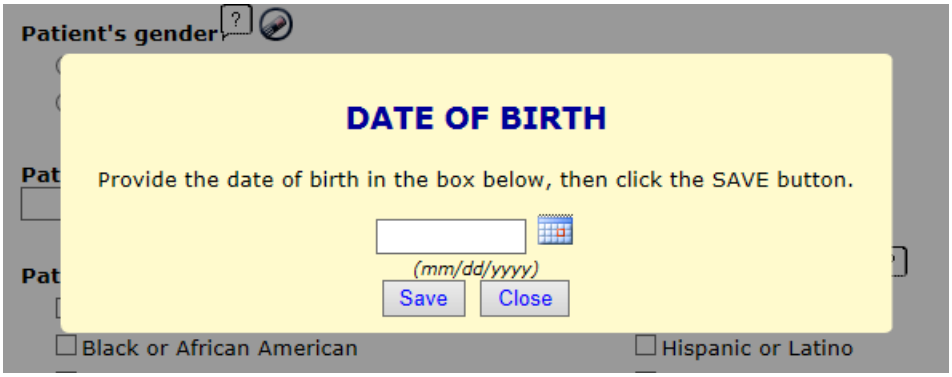
Did the patient have any of the following preexisting characteristics that may have contributed to the event? (Check all that apply)

- ☐ Allergies
- ☐ Alcohol/drug use
- ☐ COPD
- ☐ Coronary heart disease
- ☐ Diabetes
- ☐ Hepatic/renal dysfunction
- ☐ Hypertension
- ☐ Immuno-compromised
- ☐ Morbidly obese
- ☐ Pneumonia
- ☐ Pregnancy
- ☐ Premature infant
- ☐ Smoking
- ☐ Stroke
- ☐ Surgery
- ☐ Relevant accidents (e.g. Hit head)
- ☐ Other
- ☐ No preexisting characteristics
- ☐ Not known
- ☐ Not applicable

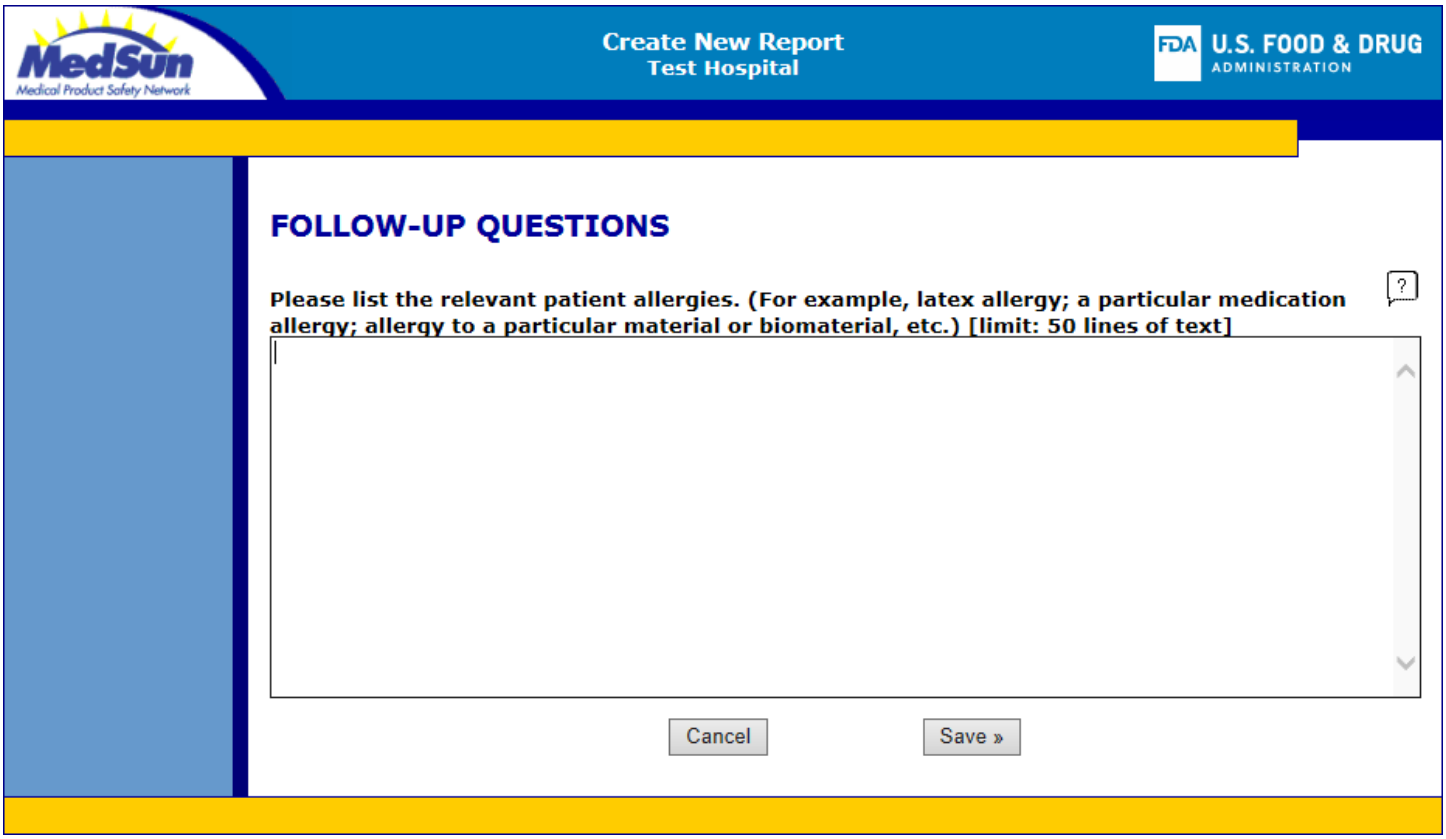
Please provide any other information about the patient that may have influenced the outcome of the event. [limit: 50 lines of text]

Cancel | Save »

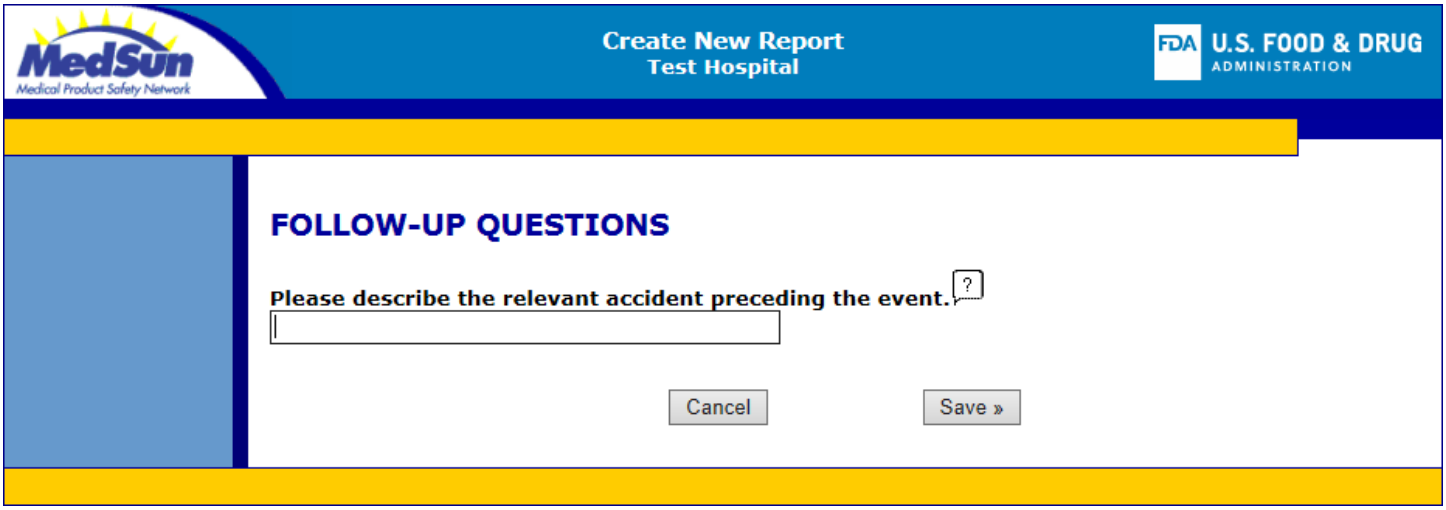
Add Report Patient Pick DOB



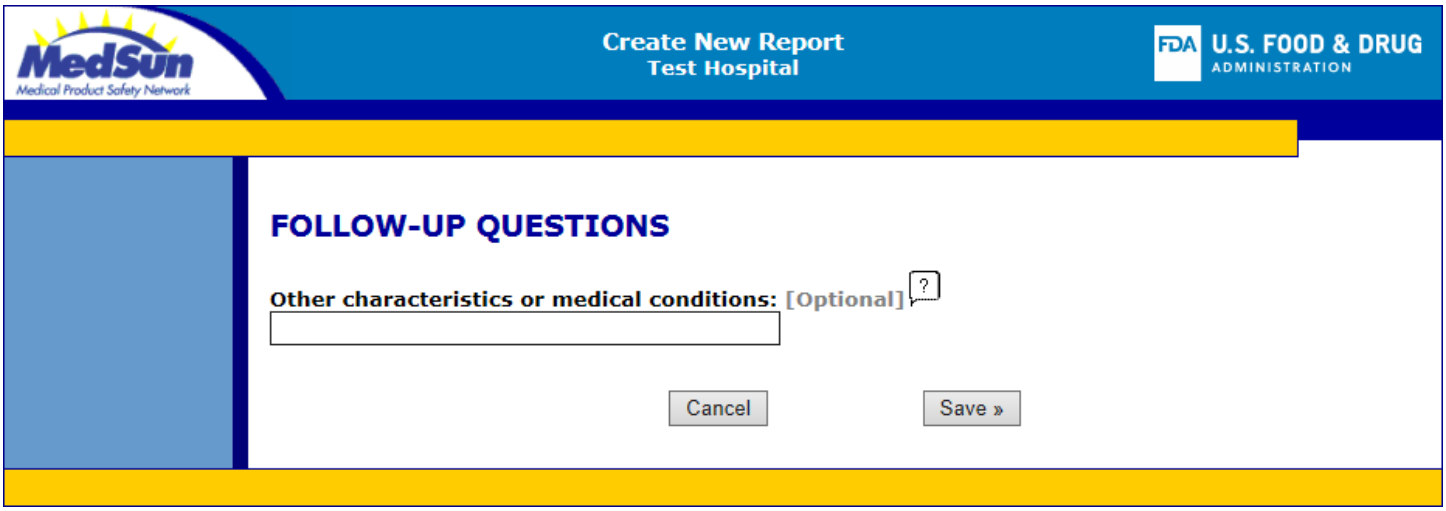
Add Report Patient Follow Up Allergies



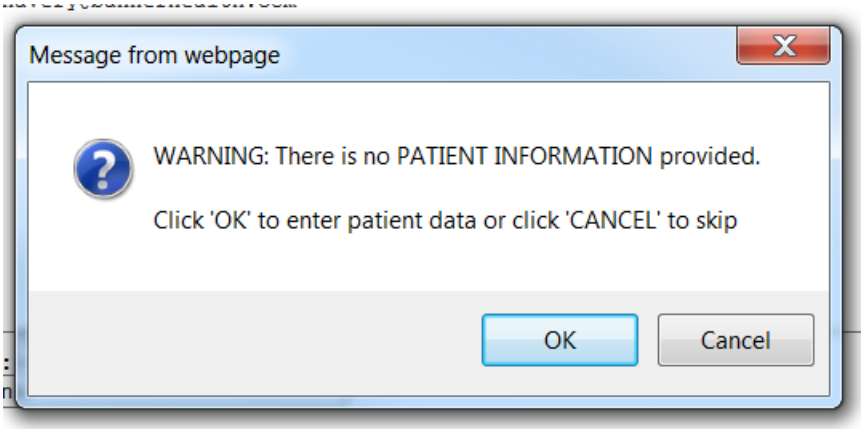
Add Report Patient Follow Up Relevant accidents



Add Report Patient Follow Up Other



Edit Report Submit Missing Patient



Edit/Add Report “Device List” Empty

Edit/Add Report “Device List”

MedSun Medical Product Safety Network

Create New Report

FDA U.S. FOOD & DRUG ADMINISTRATION

DEVICE INFORMATION

Unique Device Identifier (UDI): [?]
Parse UDI into DI and PI fields

Type of device: [?]

Device manufacturer's name: [?]

Device manufacturer's street address: (Line 1) [?]

Street address: (Line 2) [?]

City: [?]

State: [?]
(Please limit your response to 2 characters)

Zip: [?]

Device brand name: [?]

Approximate age of device: [?]
Years

If a disposable device, was the packaging saved? [Optional] [?]
○ Yes ○ No
○ Not known ○ Not applicable

Is this a single use device that was reprocessed and reused on a patient? [?]
○ Yes ○ No
○ Unknown

Is this a laboratory device or laboratory test? [?]
○ Yes ○ No

Device Identifier (DI): [?]
Query AccessGUDID

Device serial #: [?]
(Please limit your response to 30 characters)

Device model #: [?]

Device lot #: [?]
(Please limit your response to 30 characters)

Device catalog (REF) #: [?]
(Please limit your response to 30 characters)

Other device #: [?]

Expiration date: (mm/dd/yyyy) [?]

If the device was implanted, give implant date: (mm/dd/yyyy) [?]

If the device was explanted, give explant date: (mm/dd/yyyy) [?]

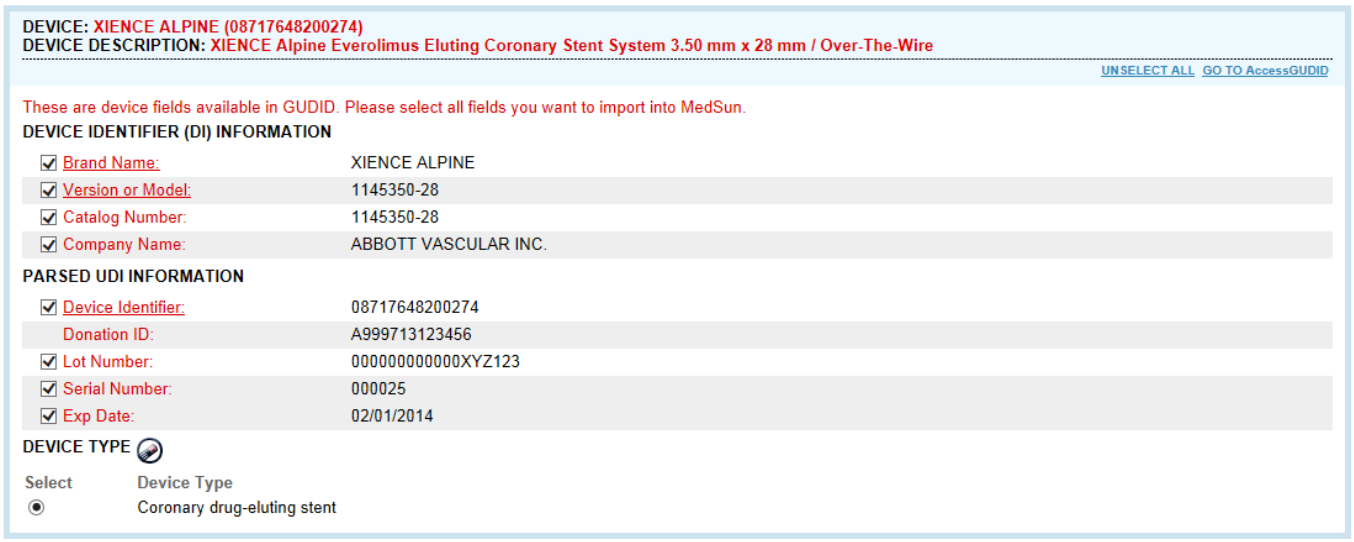
Was the device returned to the manufacturer? [?]
○ Yes ○ No
○ Not known ○ Not applicable

Is the device involved in this event available at your facility for evaluation? [?]
○ Yes ○ No
○ Not known ○ Not applicable

Have you made the manufacturer aware of this problem/issue? [?]
○ Yes ○ No
○ Unknown

Cancel Save »

Add Report Device GUDID Parse


DEVICE: XIENCE ALPINE (08717648200274)
DEVICE DESCRIPTION: XIENCE Alpine Everolimus Eluting Coronary Stent System 3.50 mm x 28 mm / Over-The-Wire

UNSELECT ALL GO TO AccessGUDID

These are device fields available in GUDID. Please select all fields you want to import into MedSun.

DEVICE IDENTIFIER (DI) INFORMATION

☑ Brand Name:	XIENCE ALPINE
☑ Version or Model:	1145350-28
☑ Catalog Number:	1145350-28
☑ Company Name:	ABBOTT VASCULAR INC.

PARSED UDI INFORMATION

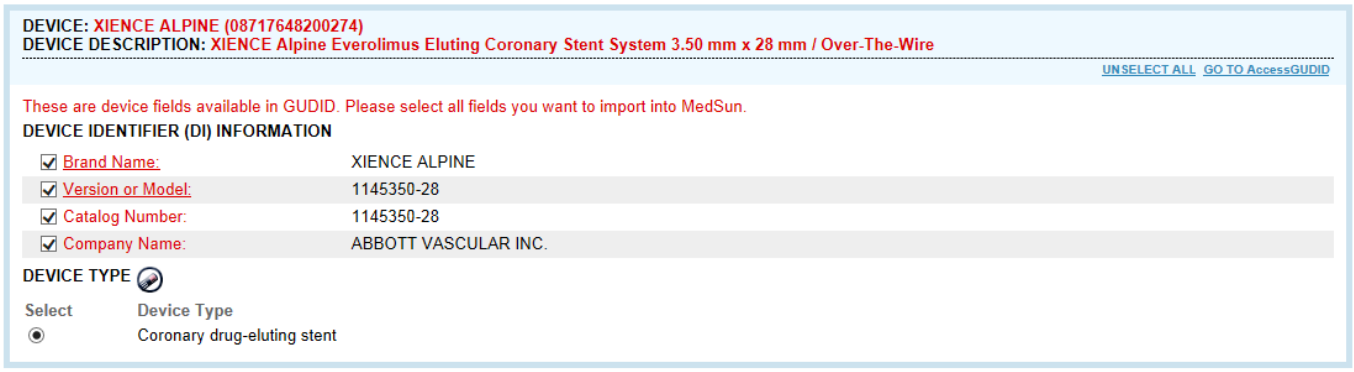
☑ Device Identifier:	08717648200274
Donation ID:	A999713123456
☑ Lot Number:	000000000000XYZ123
☑ Serial Number:	000025
☑ Exp Date:	02/01/2014

DEVICE TYPE

Select	Device Type
◉	Coronary drug-eluting stent

Submit Cancel

Add Report Device GUDID Query


DEVICE: XIENCE ALPINE (08717648200274)
DEVICE DESCRIPTION: XIENCE Alpine Everolimus Eluting Coronary Stent System 3.50 mm x 28 mm / Over-The-Wire

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DEVICE IDENTIFIER (DI) INFORMATION

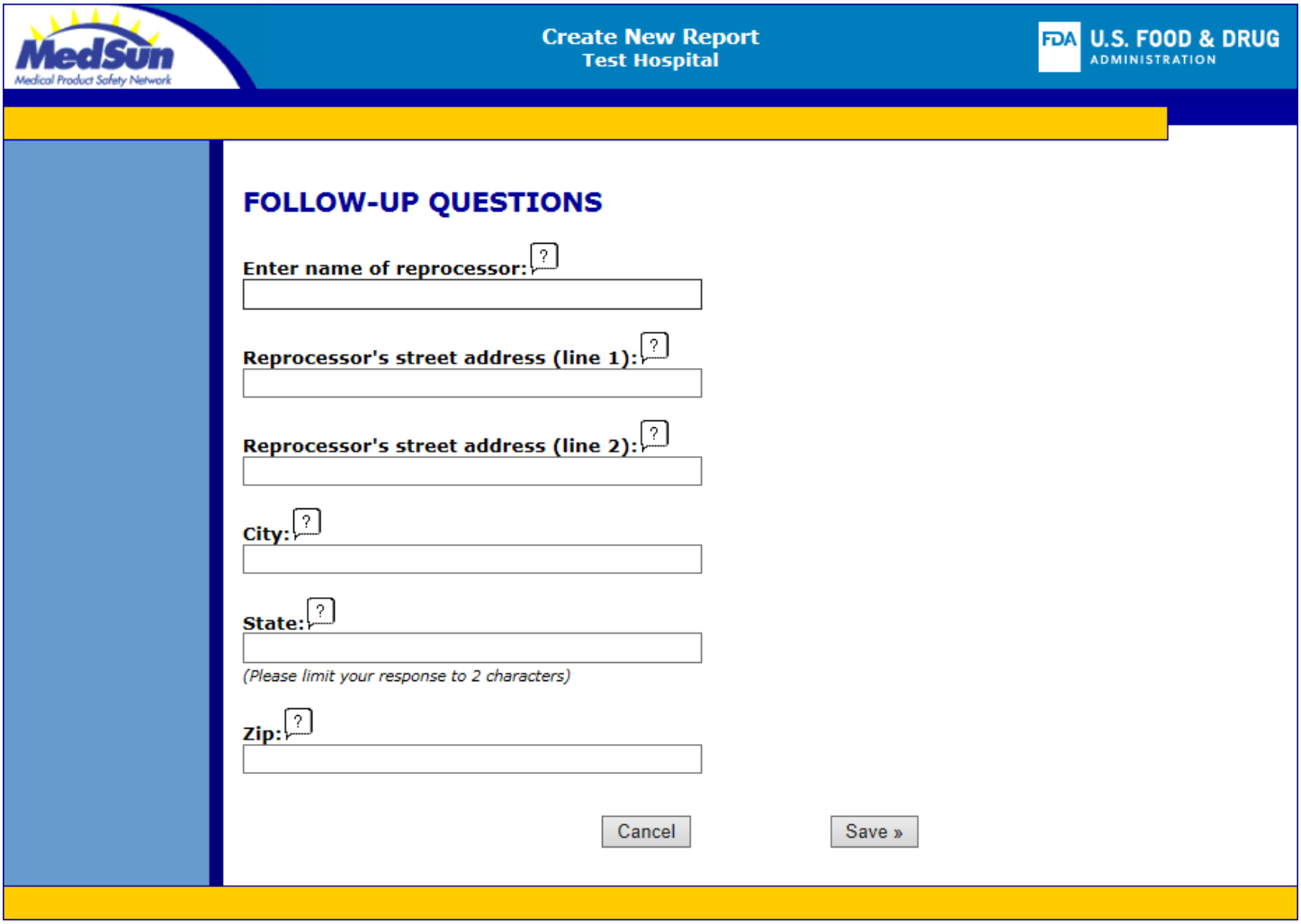
☑ Brand Name:	XIENCE ALPINE
☑ Version or Model:	1145350-28
☑ Catalog Number:	1145350-28
☑ Company Name:	ABBOTT VASCULAR INC.

DEVICE TYPE

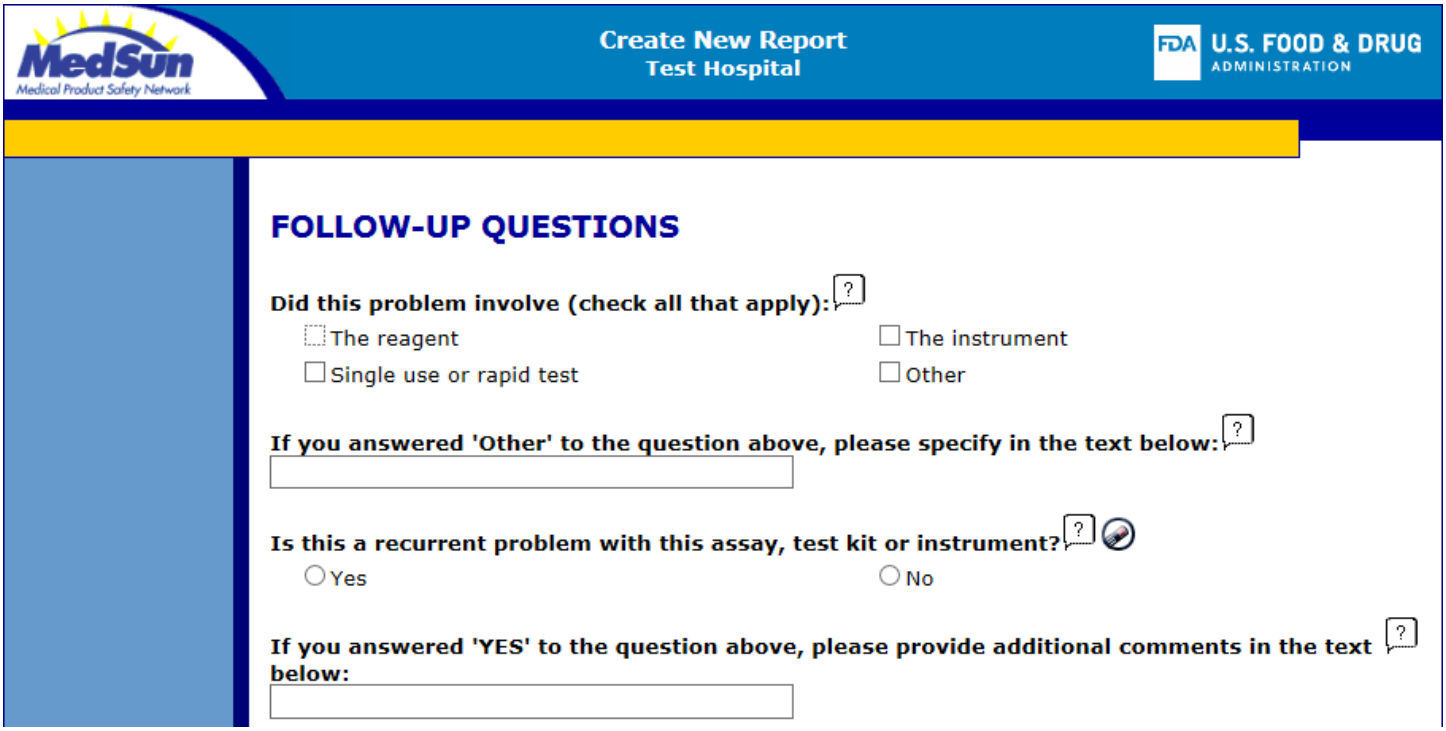
Select	Device Type
◉	Coronary drug-eluting stent

Submit Cancel

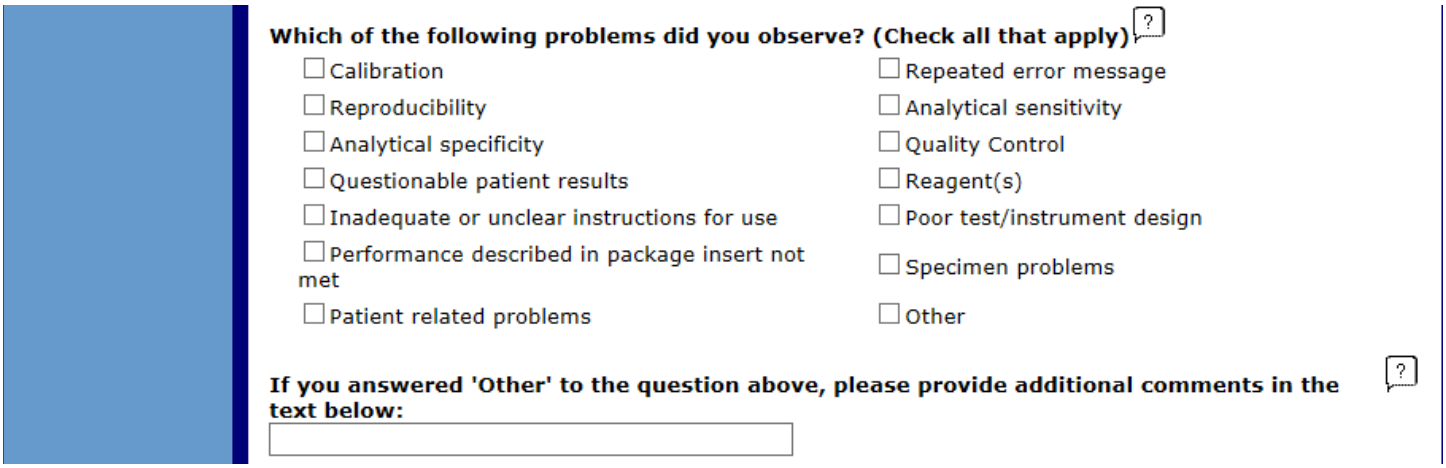
Add Report Device Follow Up Reprocessor



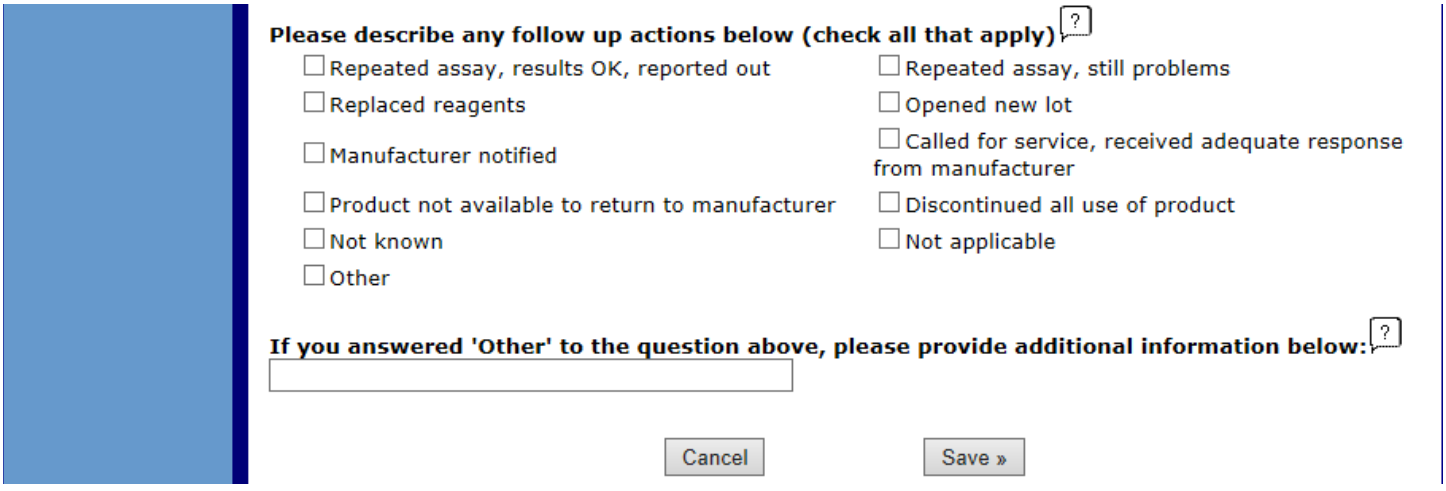
Add Report Device Follow Up LabDevice_1



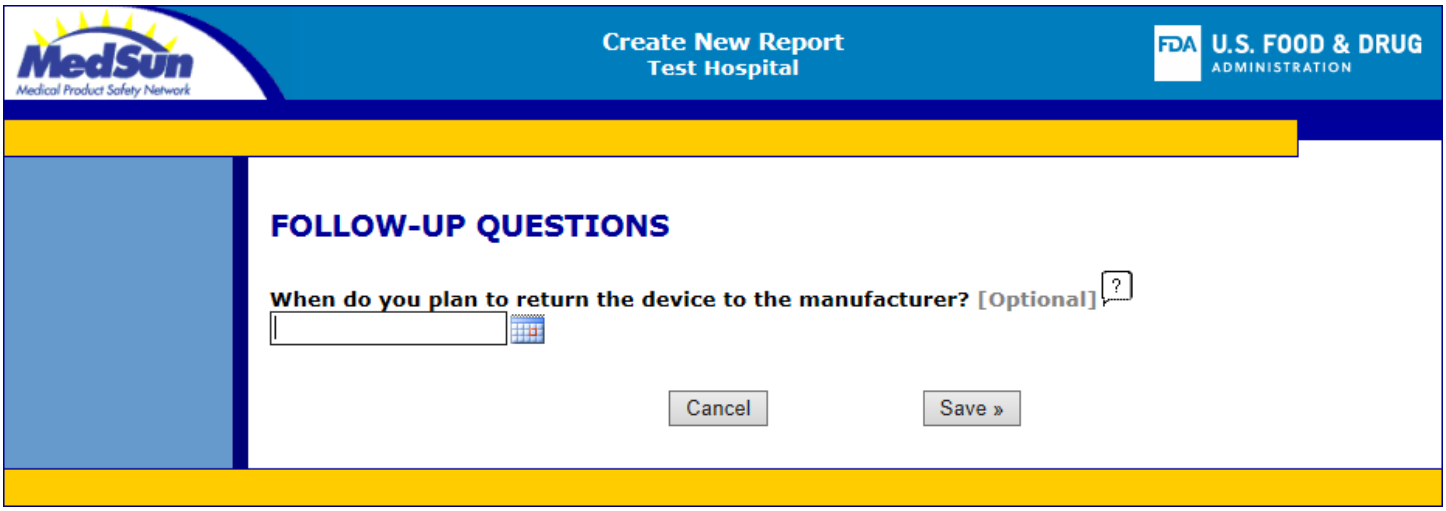
Add Report Device Follow Up LabDevice_2



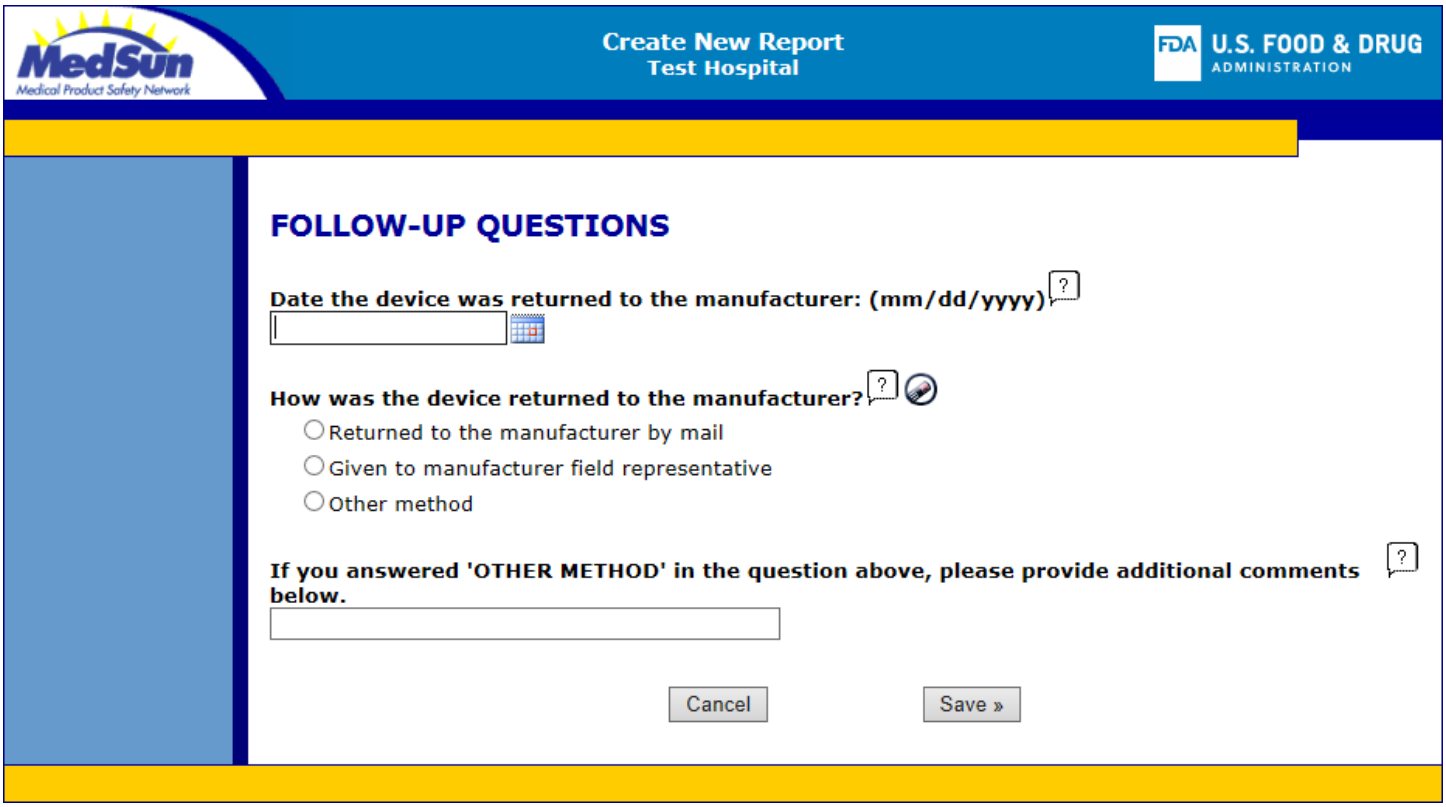
Add Report Device Follow Up LabDevice_3



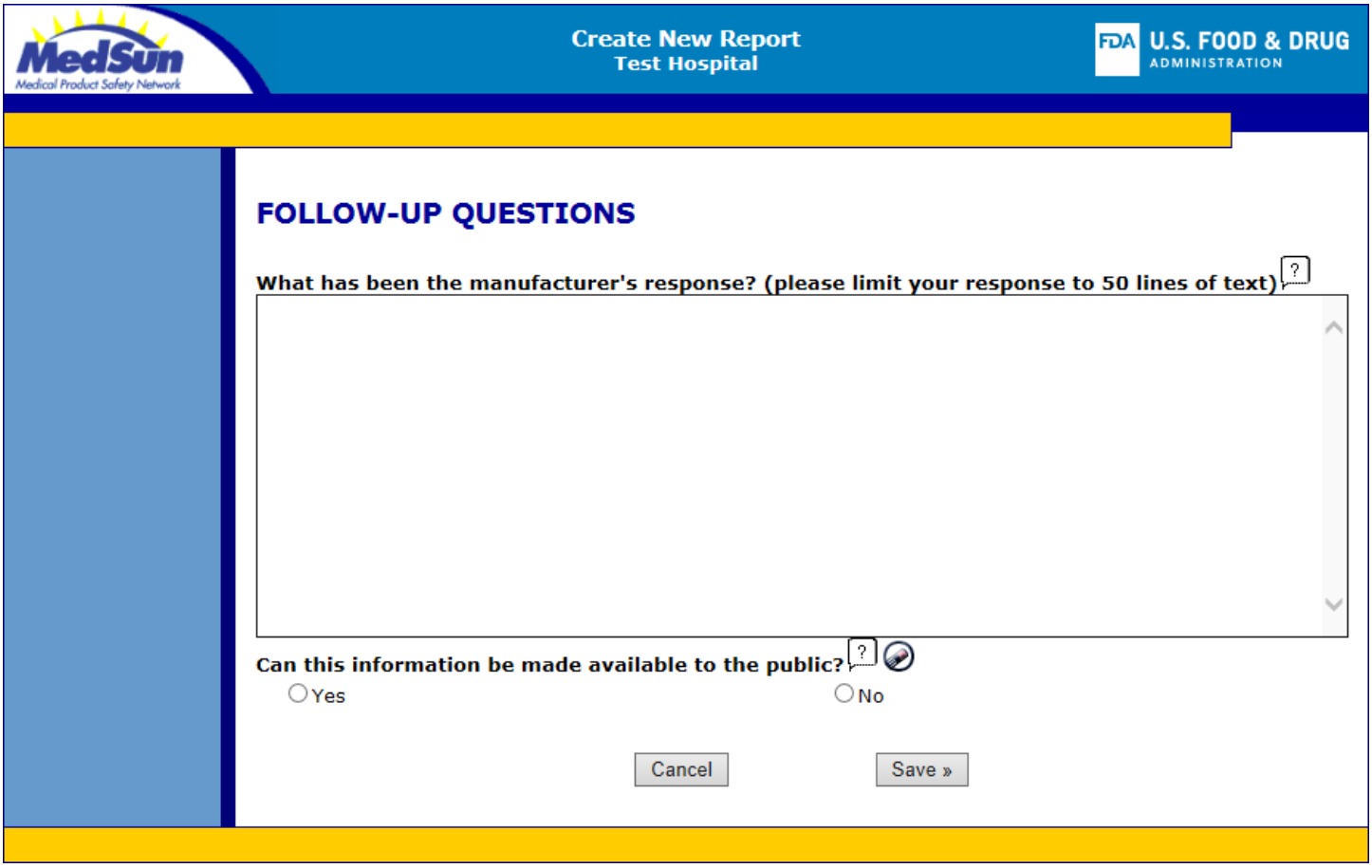
Add Report Device Follow Up MfrReturnDate



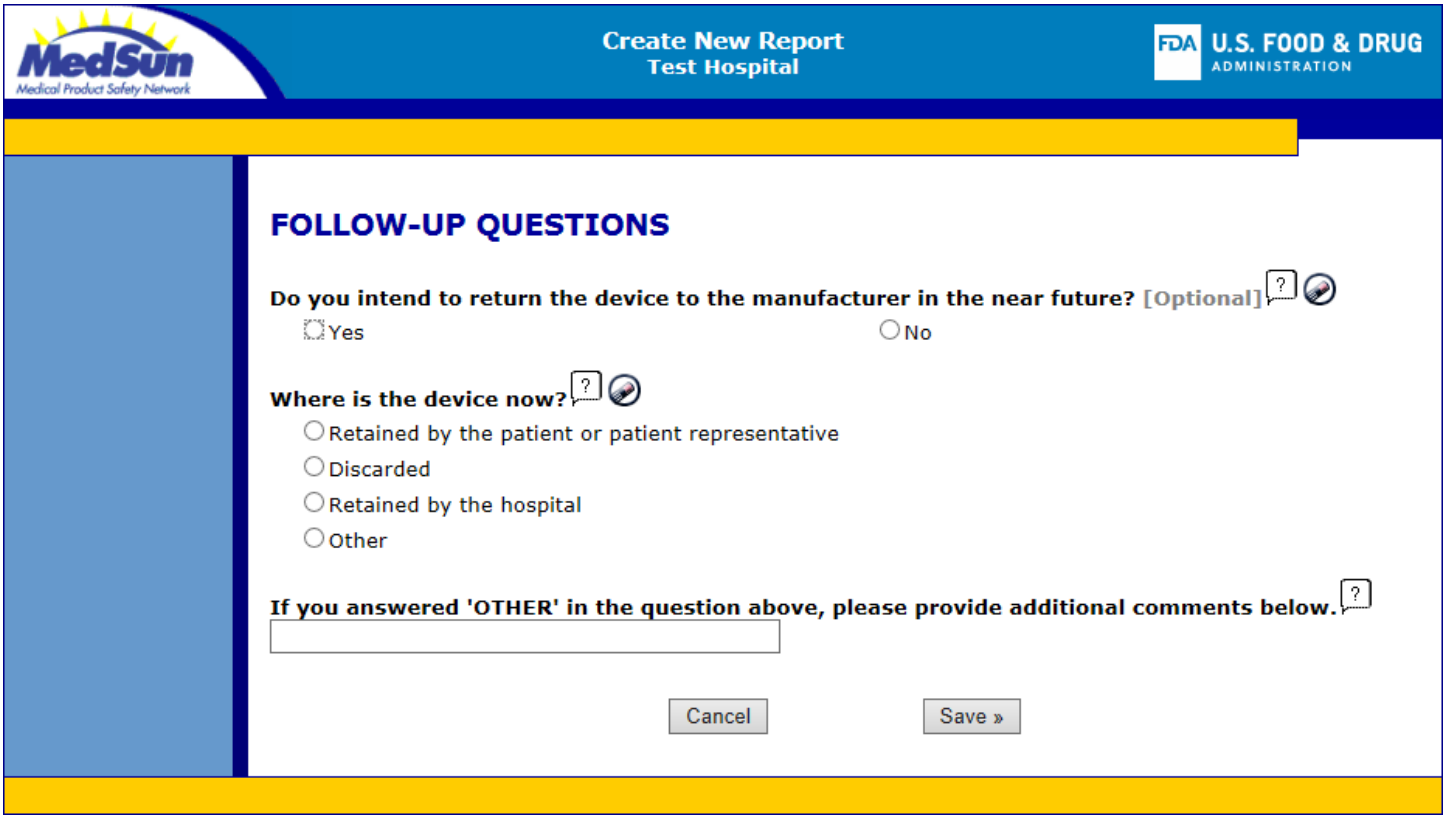
Add Report Device Follow Up MfrReturn



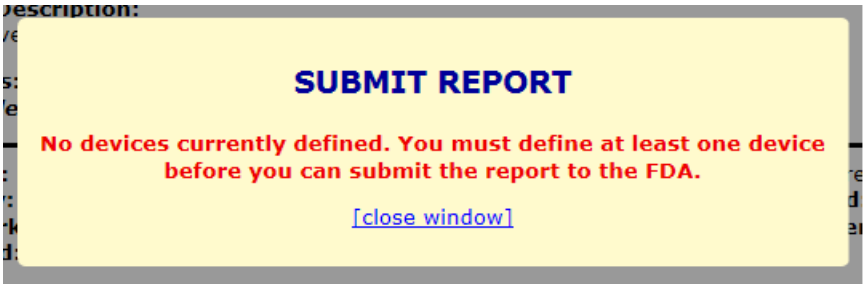
Add Report Device Follow Up MfrResponse



Add Report Device Follow Up MfrNoReturn



Edit Report Submit Missing Device



Save Options

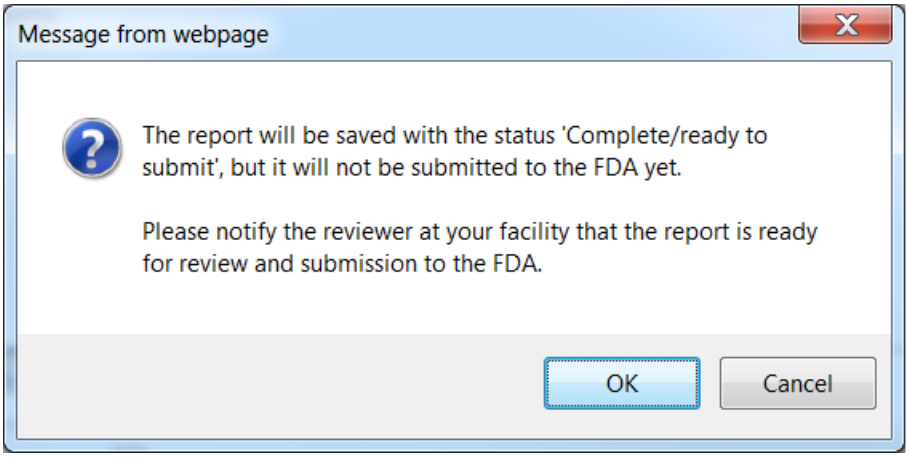
Edit Report Save Continue

Edit Report Save Continue Ready To Submit

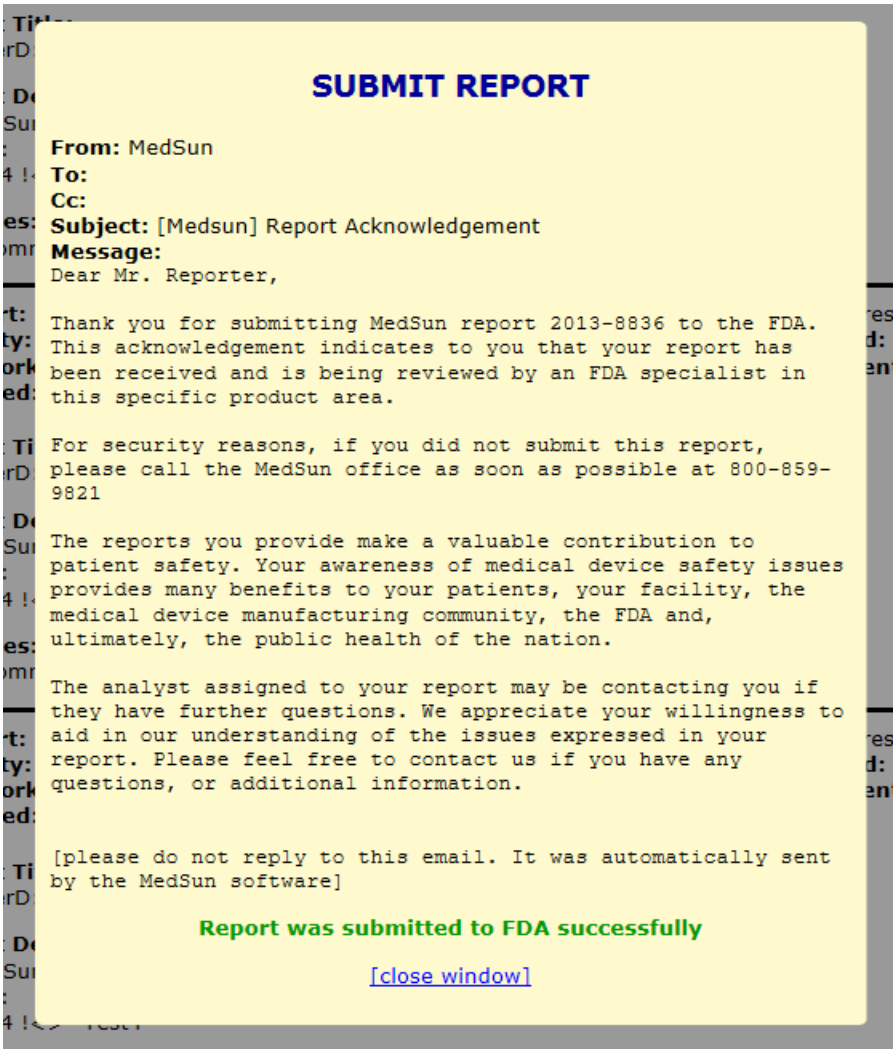
Edit Report Save Exit Without Status

Edit Report Save Exit

Edit Report Save Exit Popup

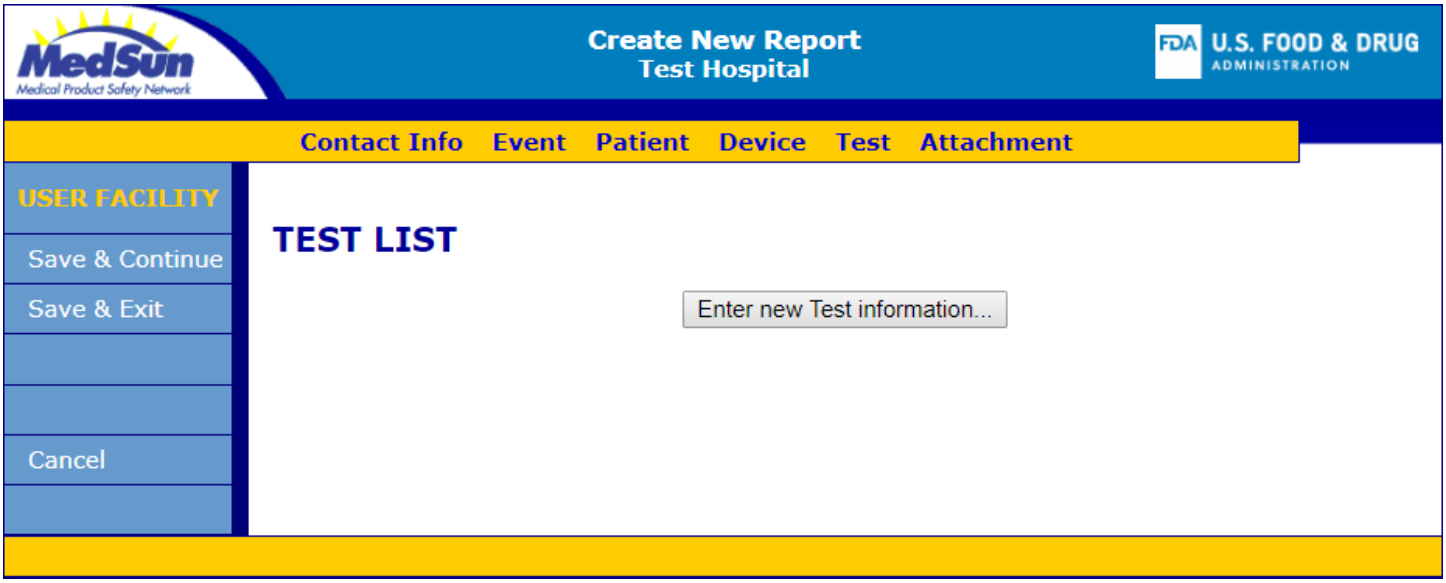


Edit Report Submit Confirmation

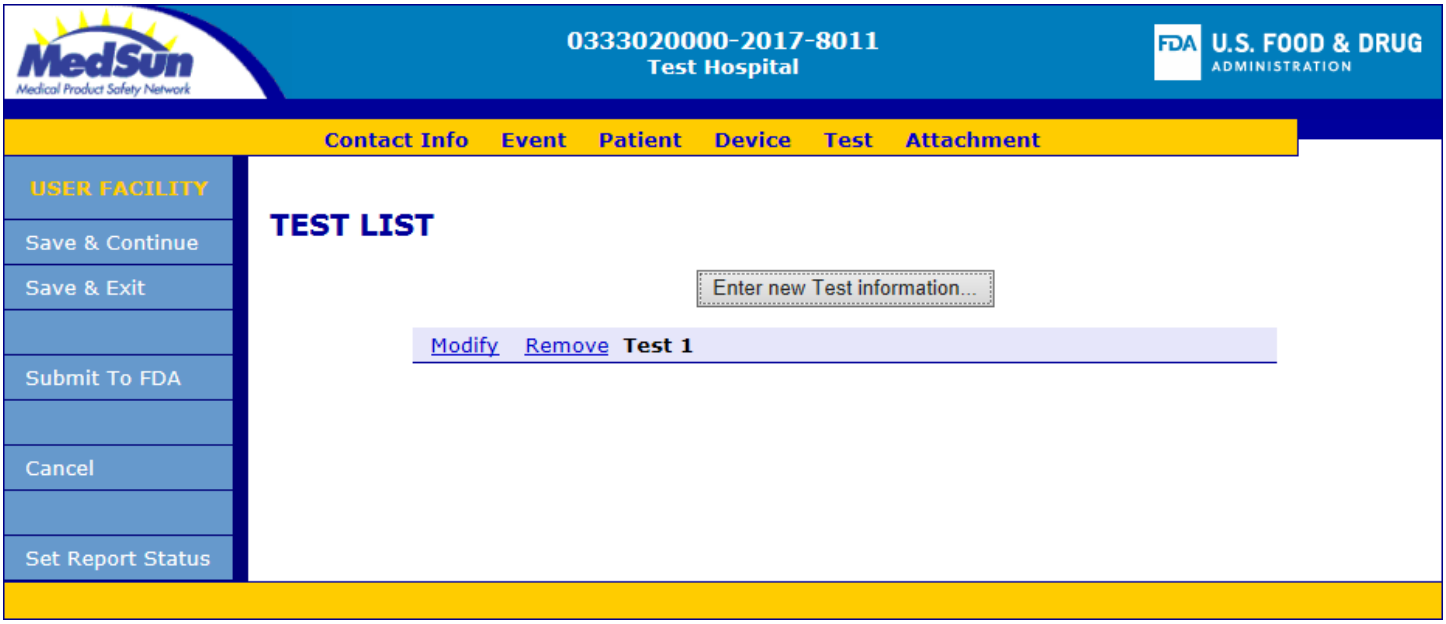


Test

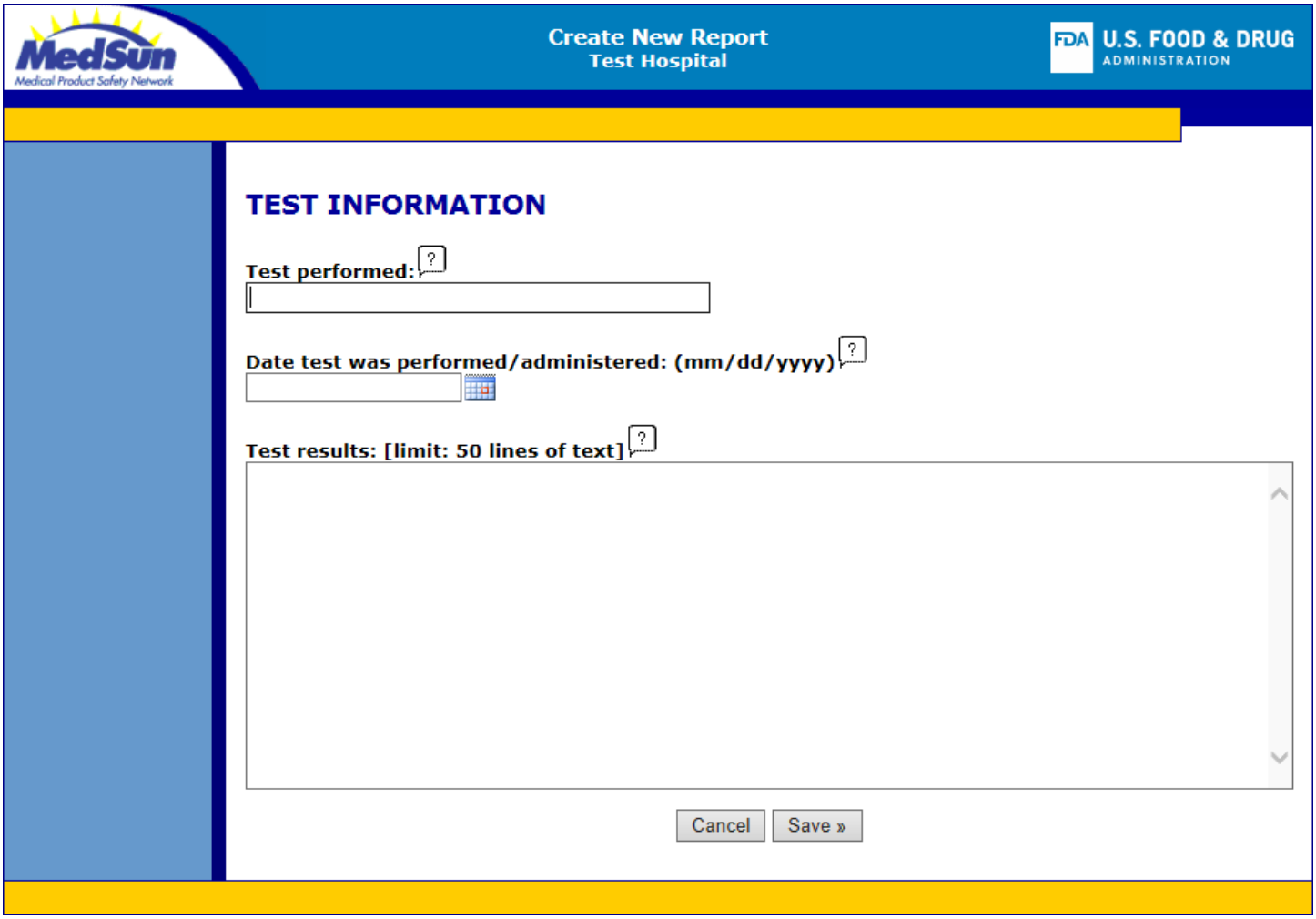
Add Report Test List Empty



Add Report Test List

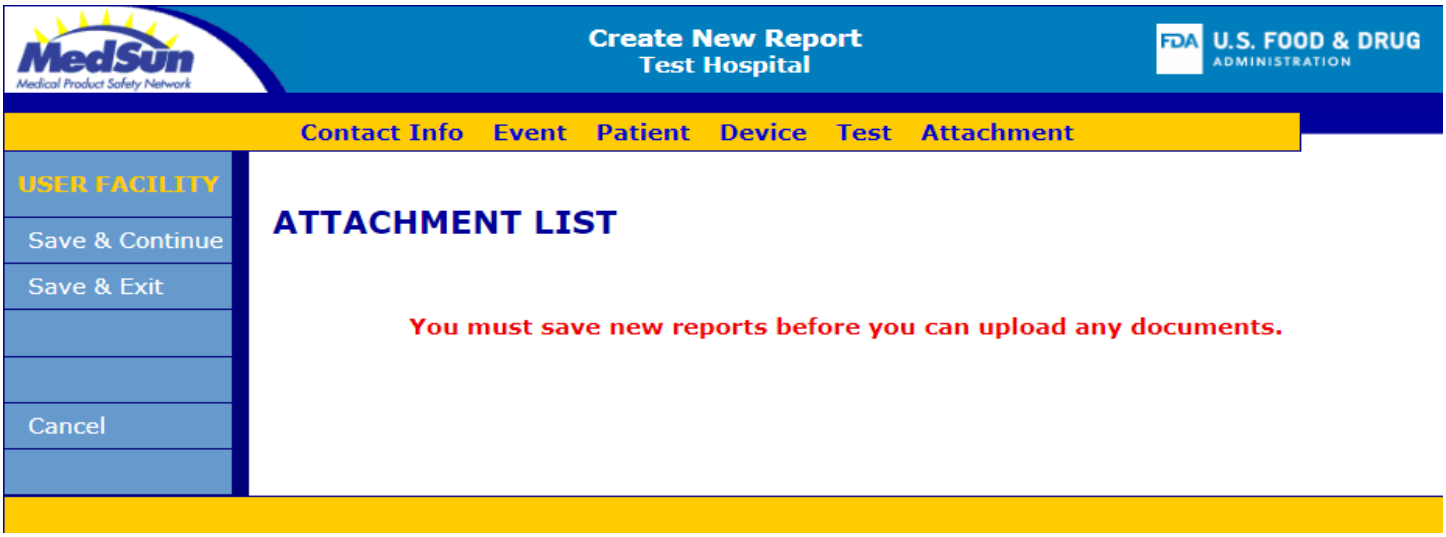


Add Report Test

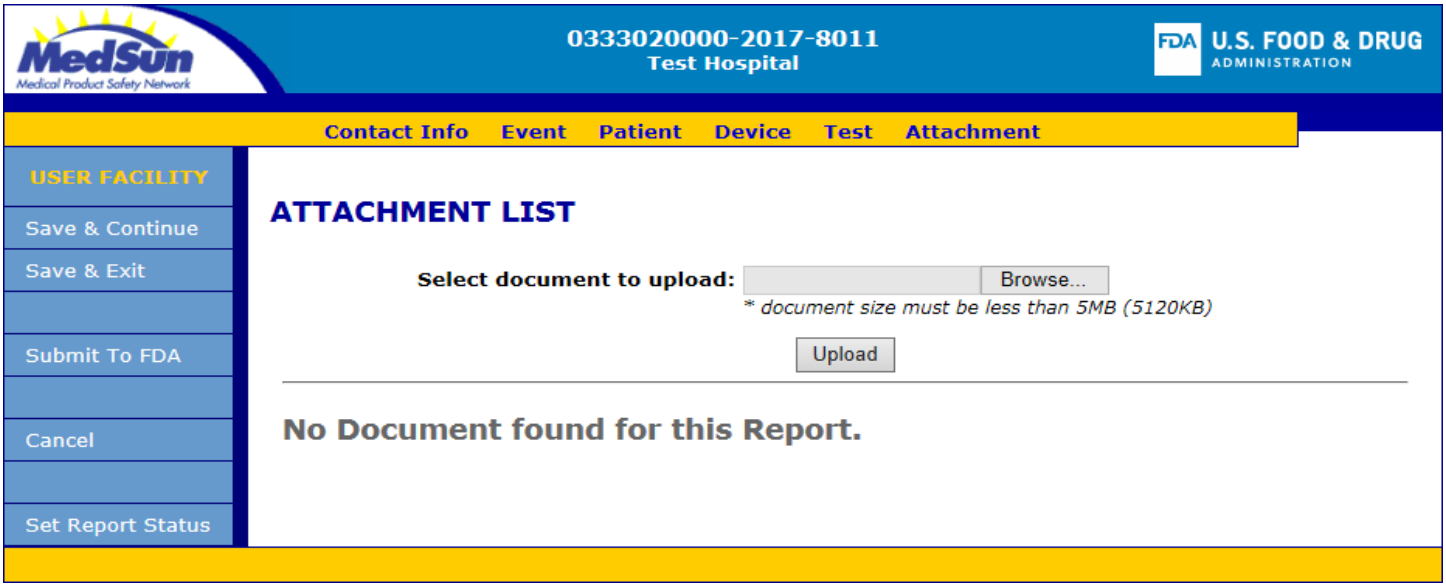


Attachment

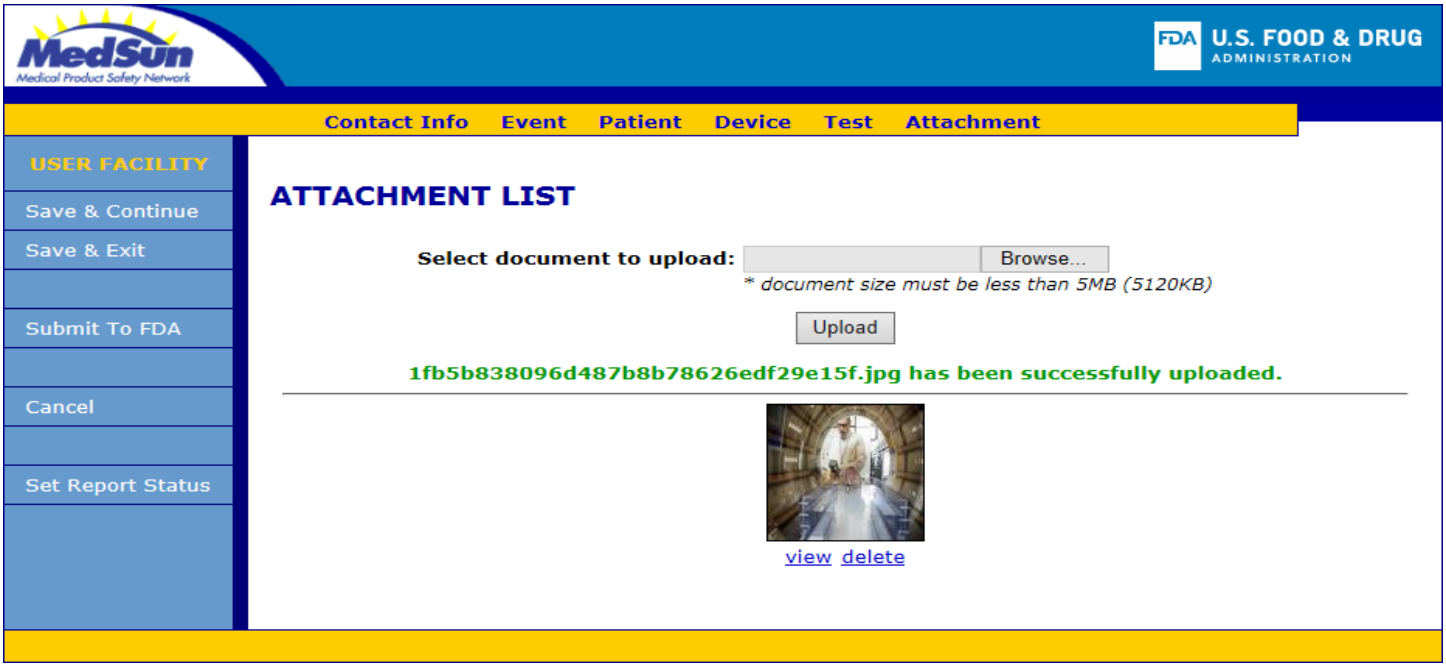
Edit/Add Report “Attachment List” Empty

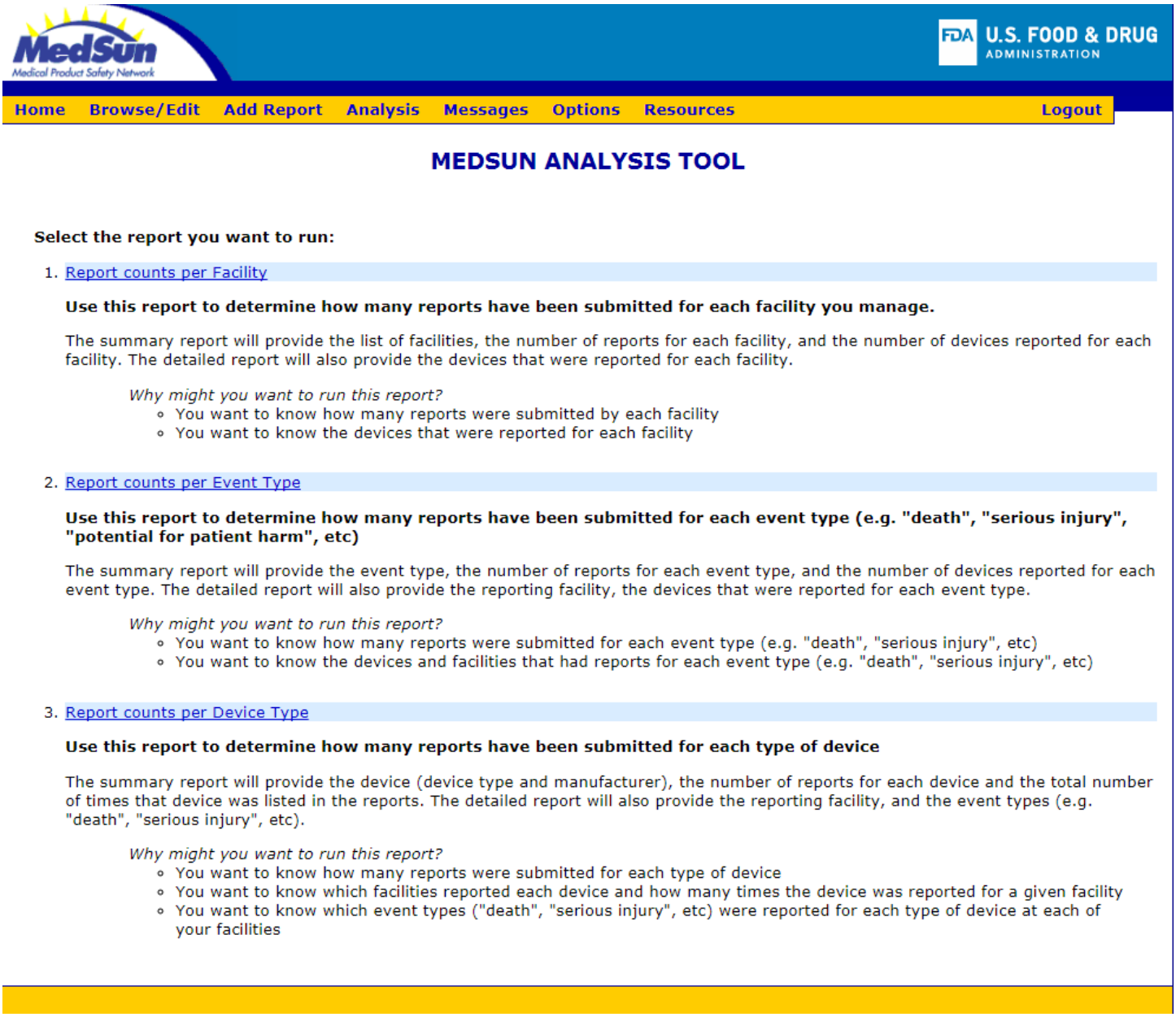


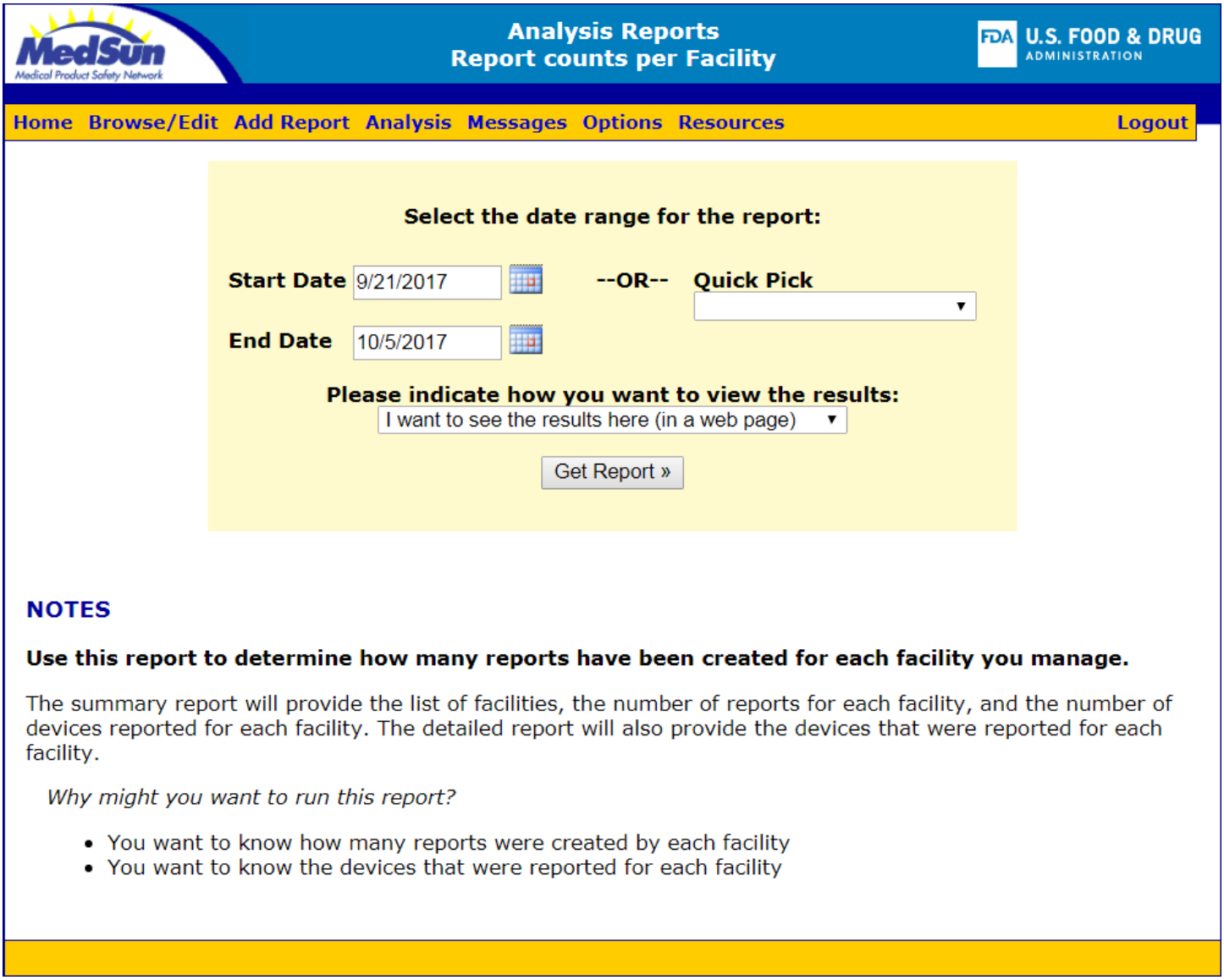
Edit/Add Report “Attachment List”

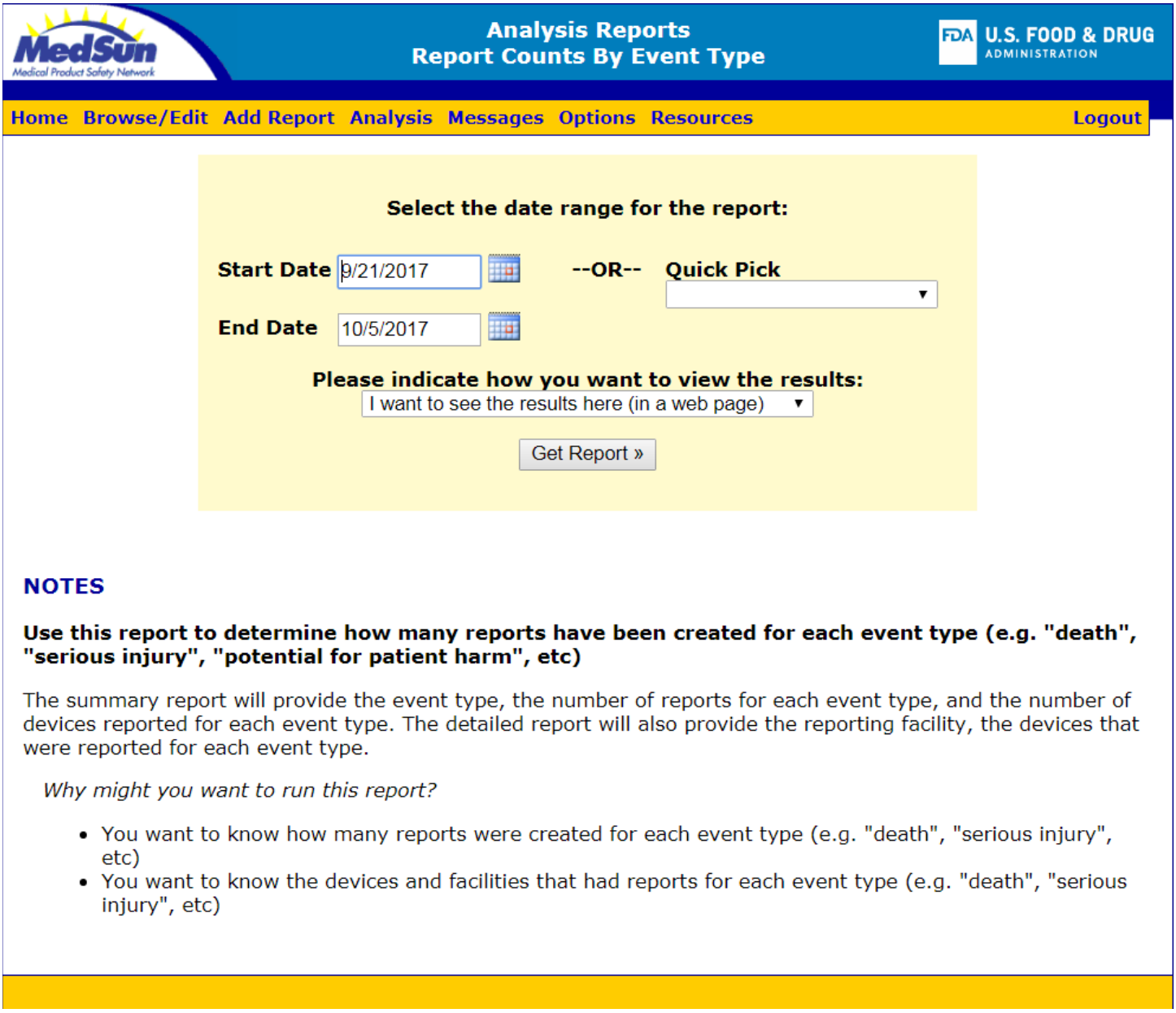


Edit/Add Report “Attachment List” Success




MedSun
Medical Product Safety Network
FDA U.S. FOOD & DRUG ADMINISTRATION
Home Browse/Edit Add Report Analysis Messages Options Resources Logout
MEDSUN ANALYSIS TOOL
Select the report you want to run:
1. Report counts per Facility
Use this report to determine how many reports have been submitted for each facility you manage.
The summary report will provide the list of facilities, the number of reports for each facility, and the number of devices reported for each facility. The detailed report will also provide the devices that were reported for each facility.
Why might you want to run this report?
You want to know how many reports were submitted by each facility
You want to know the devices that were reported for each facility
2. Report counts per Event Type
Use this report to determine how many reports have been submitted for each event type (e.g. "death", "serious injury", "potential for patient harm", etc)
The summary report will provide the event type, the number of reports for each event type, and the number of devices reported for each event type. The detailed report will also provide the reporting facility, the devices that were reported for each event type.
Why might you want to run this report?
You want to know how many reports were submitted for each event type (e.g. "death", "serious injury", etc)
You want to know the devices and facilities that had reports for each event type (e.g. "death", "serious injury", etc)
3. Report counts per Device Type
Use this report to determine how many reports have been submitted for each type of device
The summary report will provide the device (device type and manufacturer), the number of reports for each device and the total number of times that device was listed in the reports. The detailed report will also provide the reporting facility, and the event types (e.g. "death", "serious injury", etc).
Why might you want to run this report?
You want to know how many reports were submitted for each type of device
You want to know which facilities reported each device and how many times the device was reported for a given facility
You want to know which event types ("death", "serious injury", etc) were reported for each type of device at each of your facilities


MedSun
Medical Product Safety Network
Analysis Reports
Report counts per Facility
U.S. FOOD & DRUG ADMINISTRATION
Home Browse/Edit Add Report Analysis Messages Options Resources Logout
Select the date range for the report:
Start Date 9/21/2017
--OR--
Quick Pick
End Date 10/5/2017
Please indicate how you want to view the results:
I want to see the results here (in a web page)
Get Report »
NOTES
Use this report to determine how many reports have been created for each facility you manage.
The summary report will provide the list of facilities, the number of reports for each facility, and the number of devices reported for each facility. The detailed report will also provide the devices that were reported for each facility.
Why might you want to run this report?
You want to know how many reports were created by each facility
You want to know the devices that were reported for each facility



NOTES

Use this report to determine how many reports have been created for each event type (e.g. "death", "serious injury", "potential for patient harm", etc)

The summary report will provide the event type, the number of reports for each event type, and the number of devices reported for each event type. The detailed report will also provide the reporting facility, the devices that were reported for each event type.

Why might you want to run this report?

- You want to know how many reports were created for each event type (e.g. "death", "serious injury", etc)
- You want to know the devices and facilities that had reports for each event type (e.g. "death", "serious injury", etc)

MedSun Medical Product Safety Network

Analysis Reports
Report Counts By Event Type

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Browse/Edit Add Report Analysis Messages Options Resources Logout

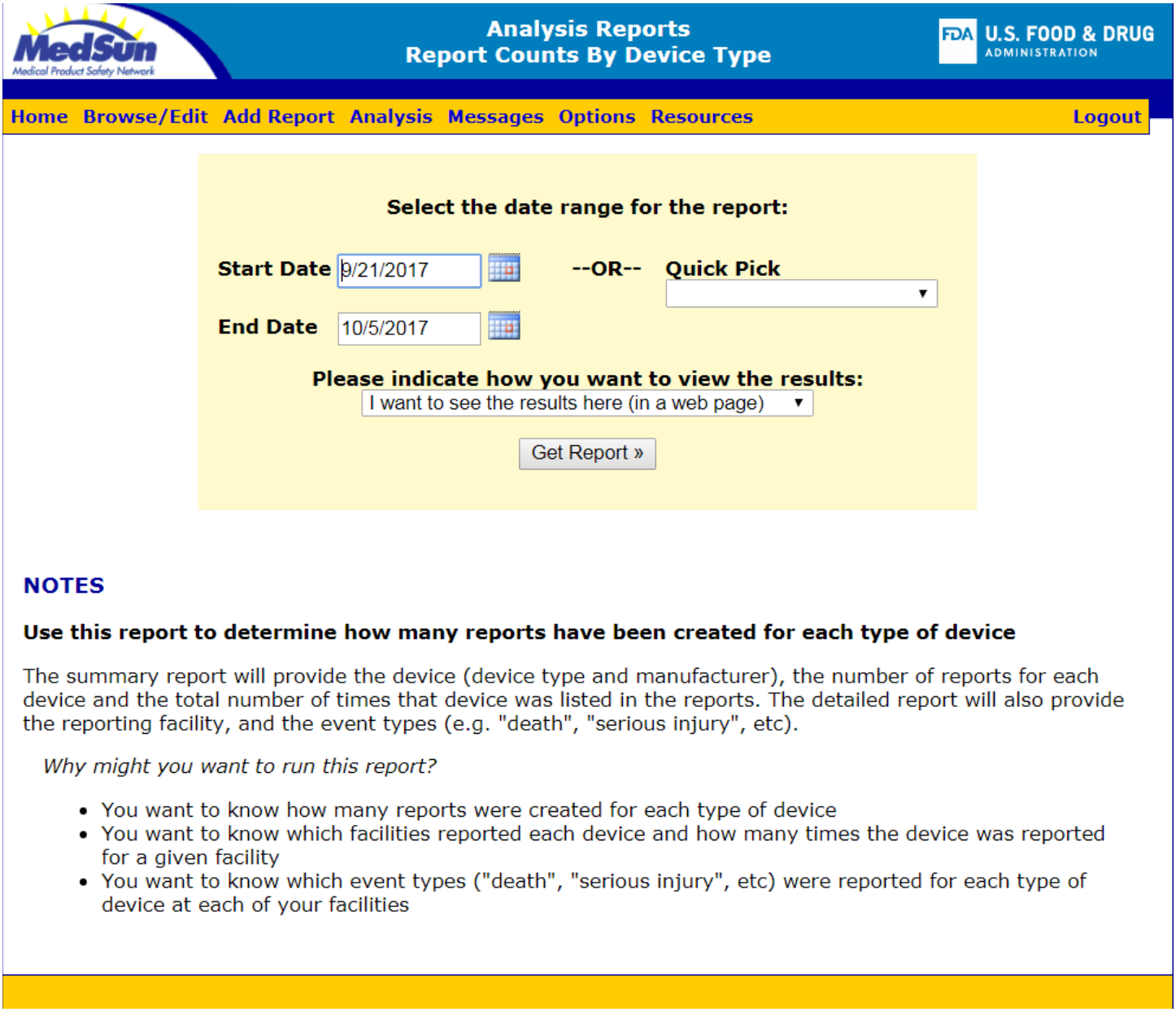
REPORT COUNTS BY EVENT TYPE

10/9/2013 to 10/23/2017 (change)

Download Summary to Excel
Download Data to Excel
Go Back to MedSun Analysis Reports

Printer Friendly
Show Detail View

Event Type	Report Count (click to view)	Device Count
Death	141	152
Serious injury	445	562
Potential harm to a health care provider [Indicates voluntary report]	5	5
Minor injury to the patient or health care provider [Indicates voluntary report]	40	40
Potential for patient harm [Indicates voluntary report]	288	391
Not known	1	1
Not applicable	2	2
test	2	0
(not answered)	82	73
-- (end of report) --		



NOTES

Use this report to determine how many reports have been created for each type of device

The summary report will provide the device (device type and manufacturer), the number of reports for each device and the total number of times that device was listed in the reports. The detailed report will also provide the reporting facility, and the event types (e.g. "death", "serious injury", etc).

Why might you want to run this report?

- You want to know how many reports were created for each type of device
- You want to know which facilities reported each device and how many times the device was reported for a given facility
- You want to know which event types ("death", "serious injury", etc) were reported for each type of device at each of your facilities

Messages

Message List

MedSun Messages

U.S. FOOD & DRUG ADMINISTRATION

Home Browse/Edit Add Report Analysis Messages Options Resources Logout

Message Topics for Mr. Reporter

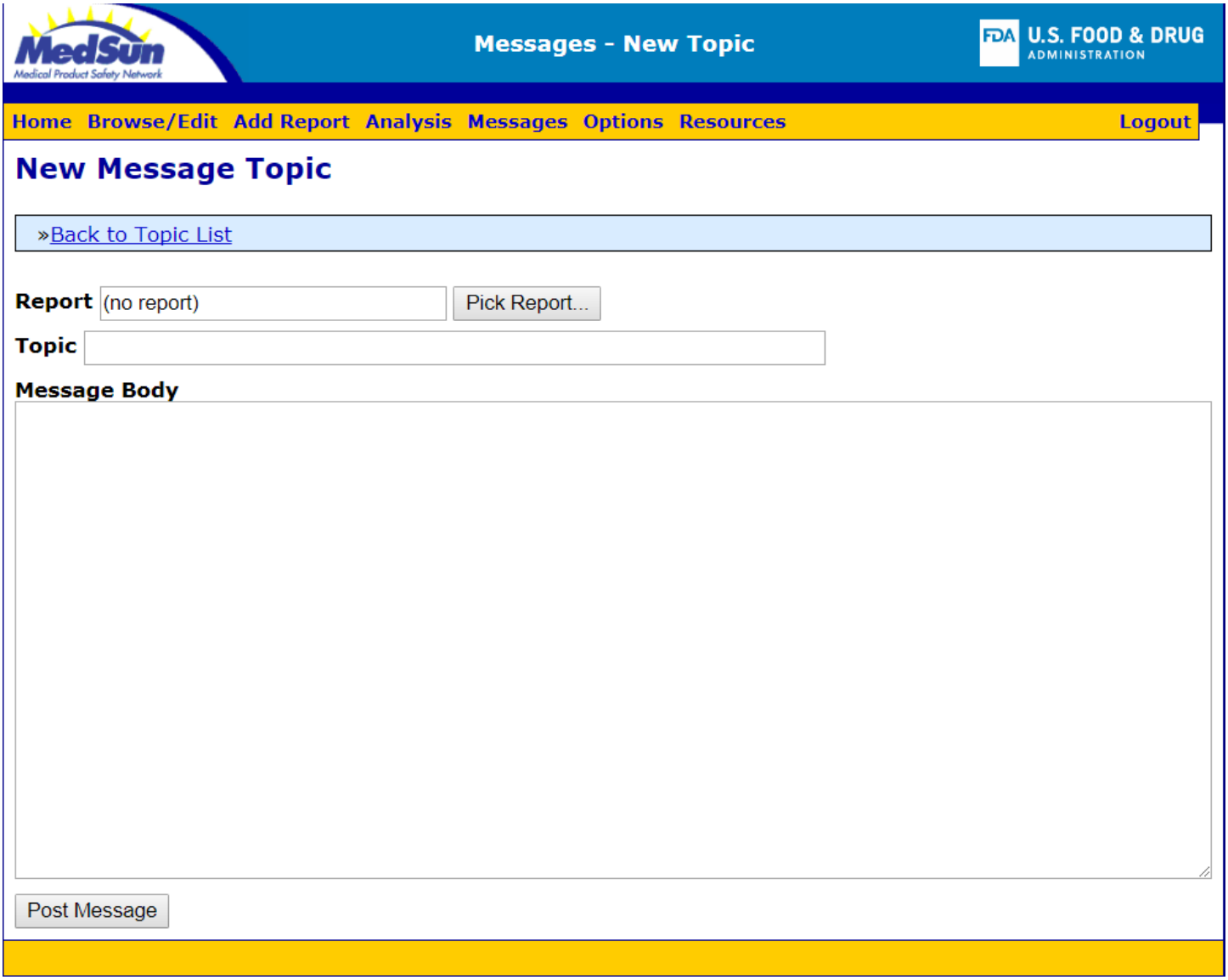
» Post a new topic

(254) record(s) found. *Page **1** of **26***

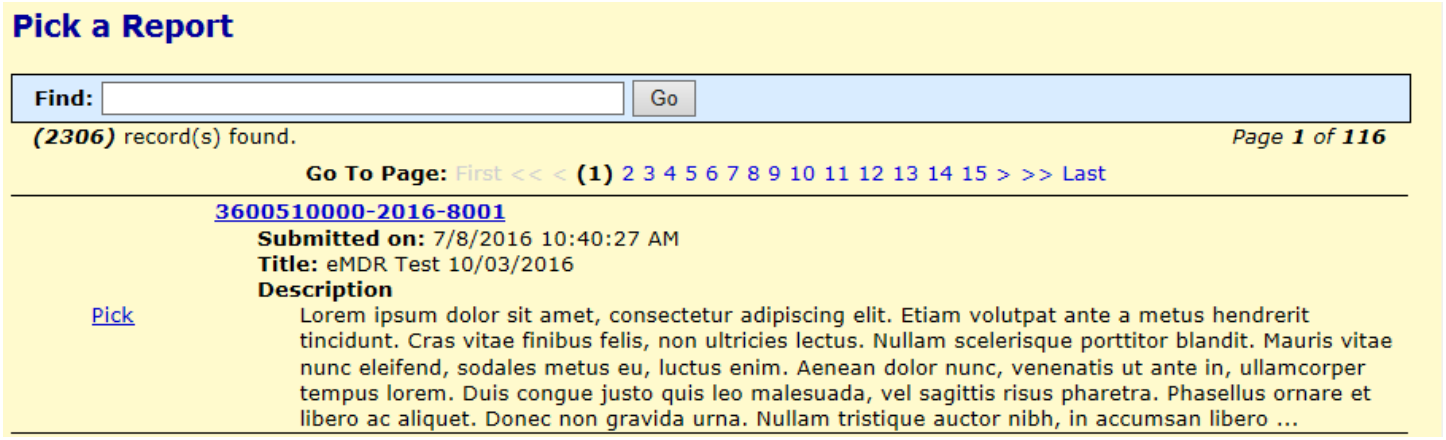
Go To Page: First << < **(1)** 2 3 4 5 6 7 8 9 10 11 12 13 14 15 > >> Last

Action	Topic
View Messages	**[Medsun] Report Acknowledgement** Message for Report **111110000-2008-8003** (view report) Created by MedSun System (MedSun) Last Message Date: 9/8/2017 2:48:05 PM (**0**) unread messages, (**9**) total messages * Messages need your response
View Messages	**Test New Delete SP** Message for Report **0333020000-2013-8844** (view report) Created by (MedSun) Last Message Date: 3/31/2017 11:42:36 AM (**2**) unread messages, (**2**) total messages * (2) UNREAD messages * Messages need your response

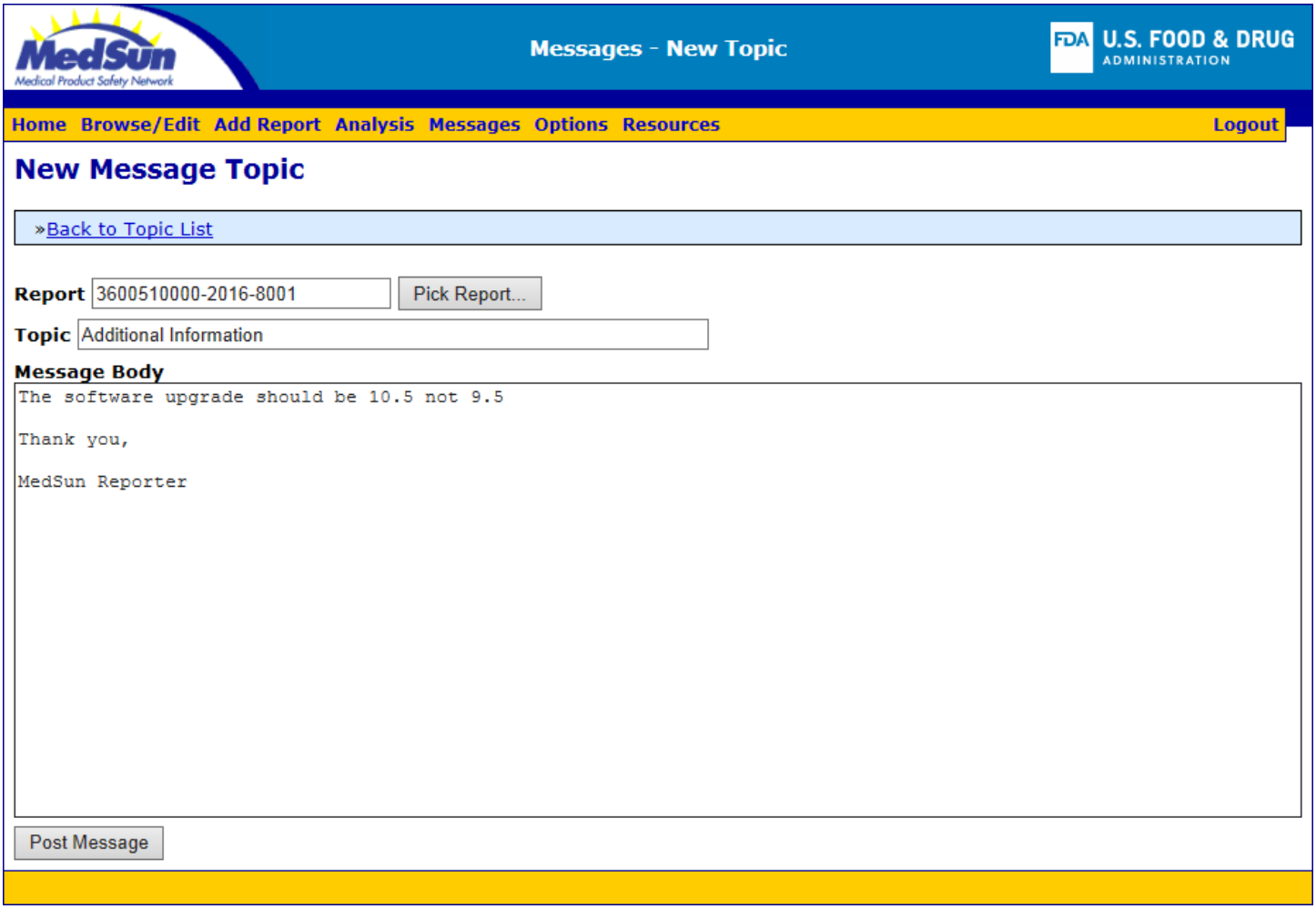
New Message Topic



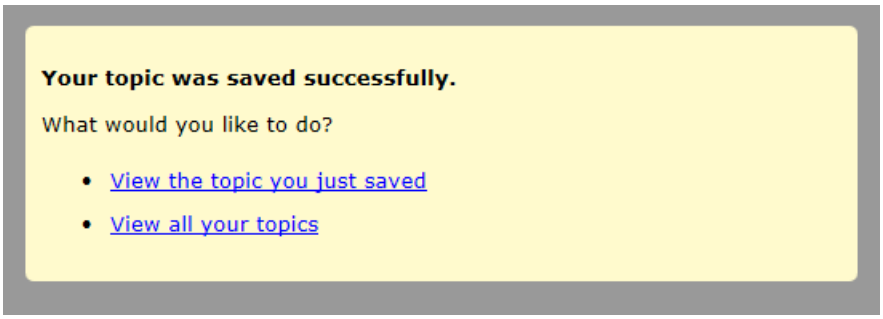
New Message Topic Pick Report



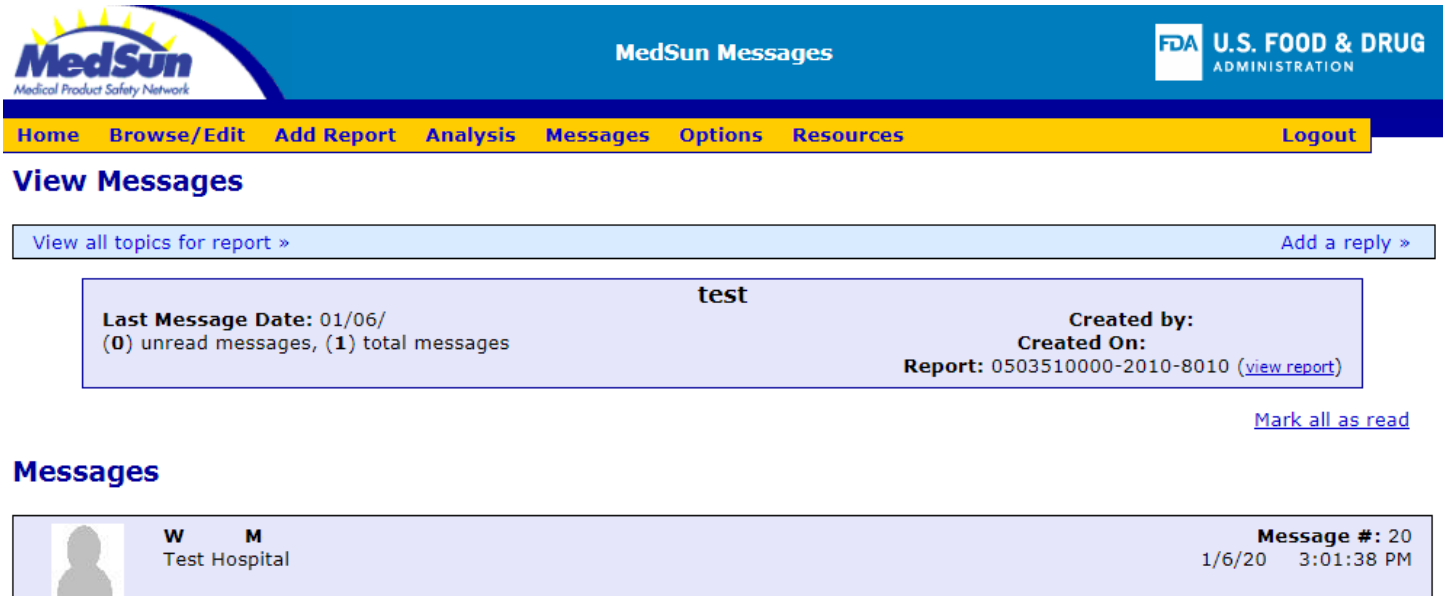
Message New Topic After Pick Report



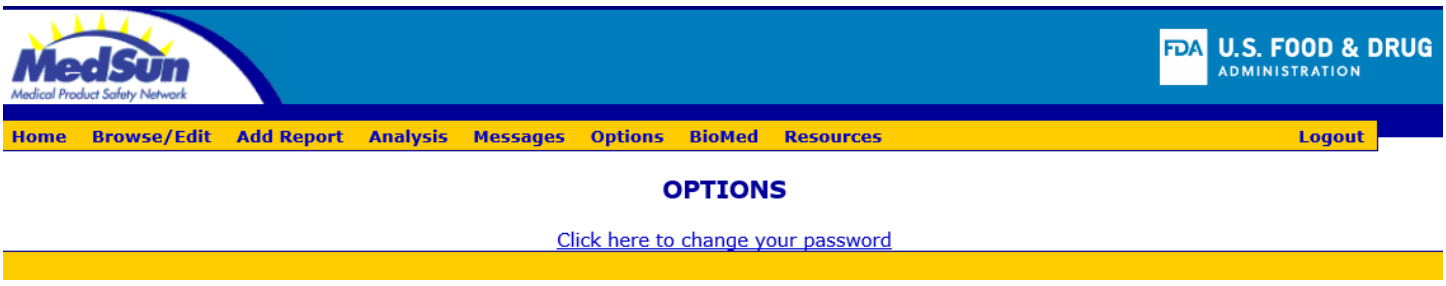
Message New Topic Post



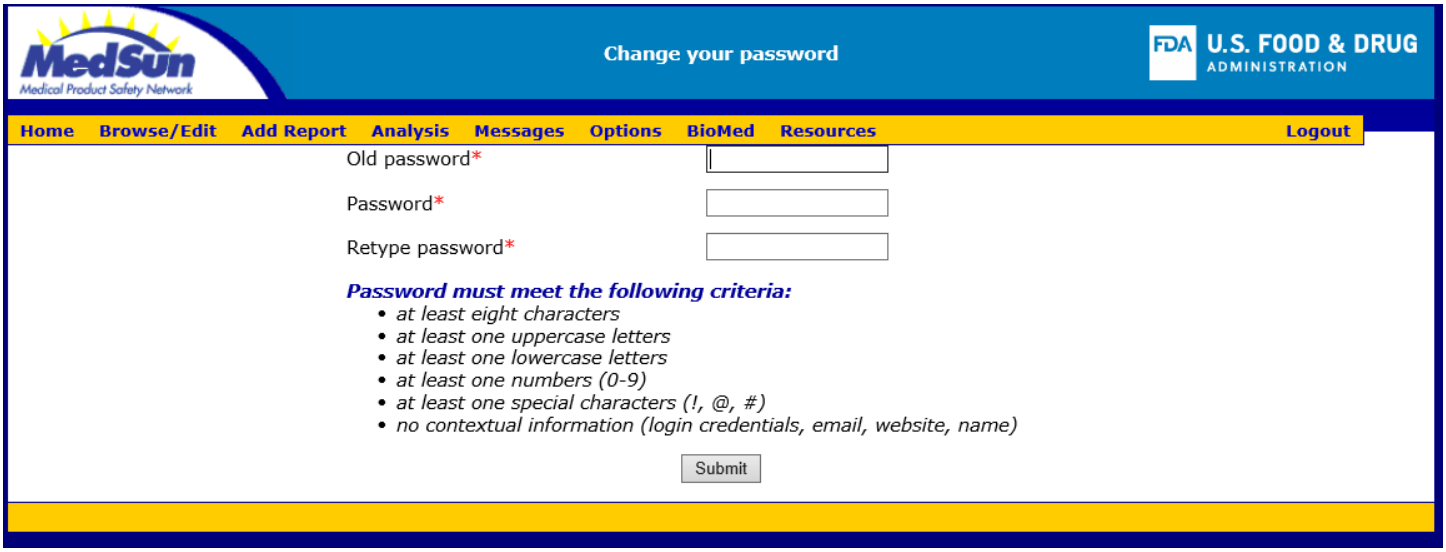
Message View Topic Message



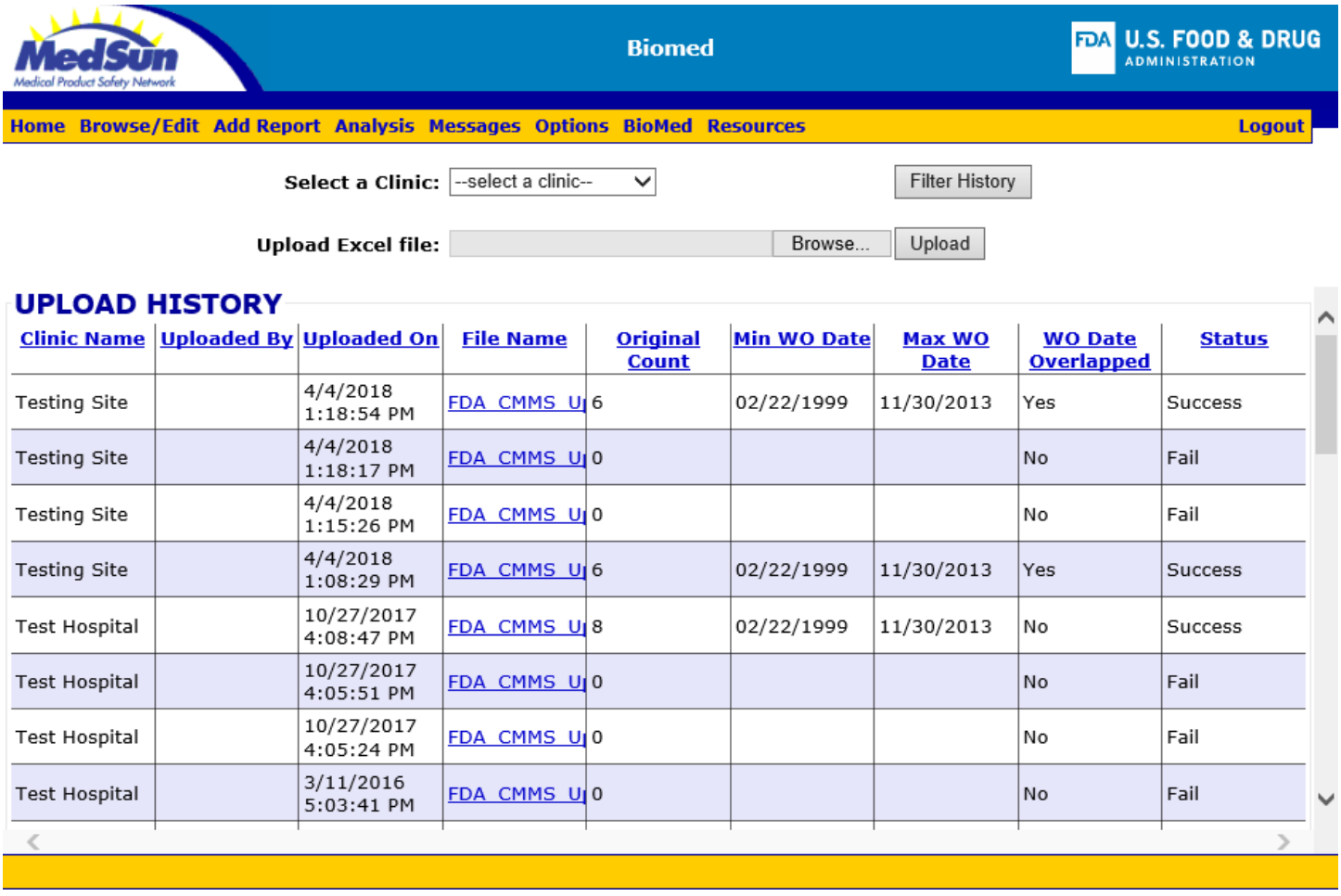
Password



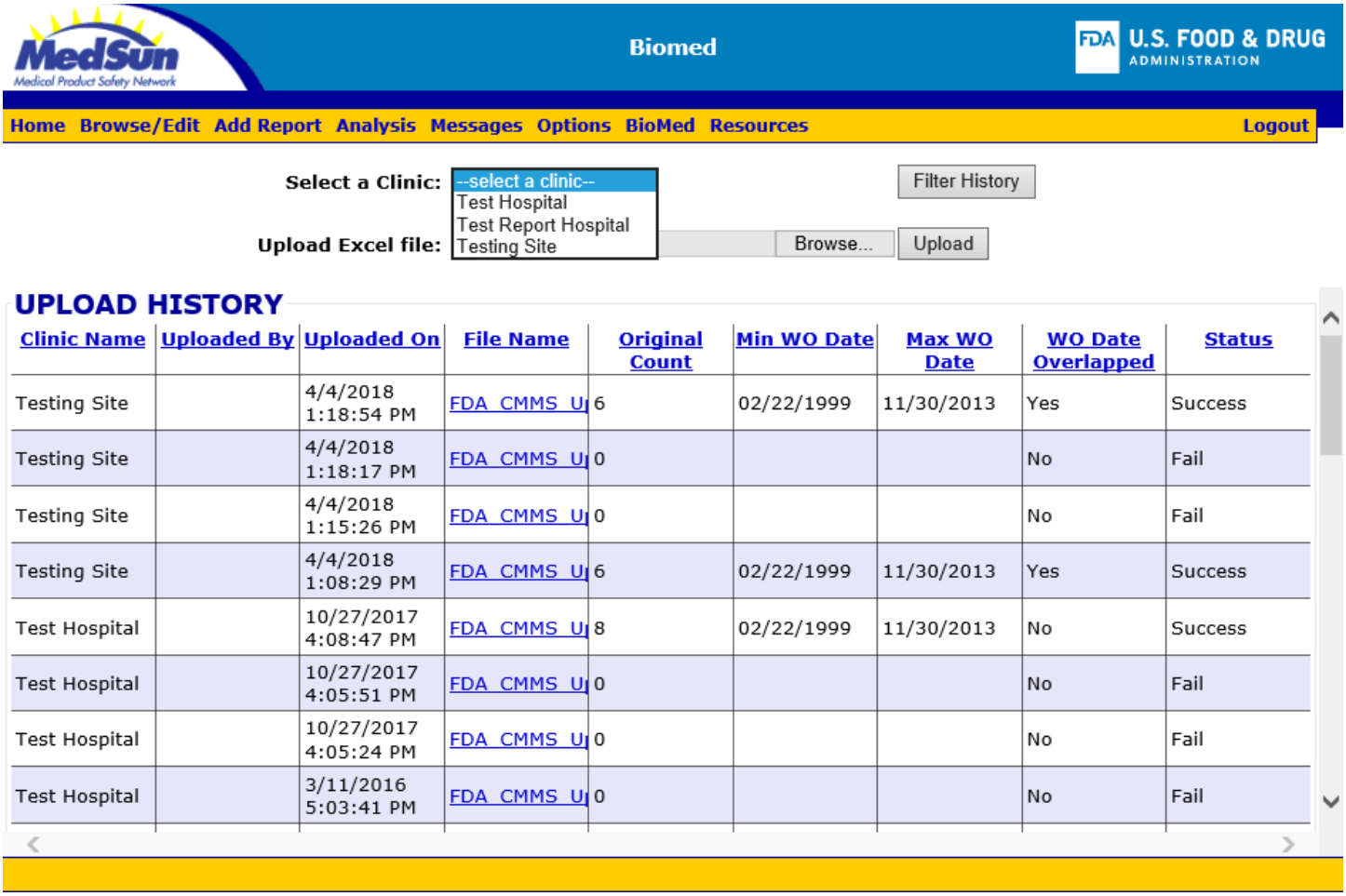
Password Reset



BioMed



Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site		4/4/2018 1:18:54 PM	FDA_CMMS_U	6	02/22/1999	11/30/2013	Yes	Success
Testing Site		4/4/2018 1:18:17 PM	FDA_CMMS_U	0			No	Fail
Testing Site		4/4/2018 1:15:26 PM	FDA_CMMS_U	0			No	Fail
Testing Site		4/4/2018 1:08:29 PM	FDA_CMMS_U	6	02/22/1999	11/30/2013	Yes	Success
Test Hospital		10/27/2017 4:08:47 PM	FDA_CMMS_U	8	02/22/1999	11/30/2013	No	Success
Test Hospital		10/27/2017 4:05:51 PM	FDA_CMMS_U	0			No	Fail
Test Hospital		10/27/2017 4:05:24 PM	FDA_CMMS_U	0			No	Fail
Test Hospital		3/11/2016 5:03:41 PM	FDA_CMMS_U	0			No	Fail


MedSun
Medical Product Safety Network
Biomed
FDA U.S. FOOD & DRUG ADMINISTRATION
Home Browse/Edit Add Report Analysis Messages Options BioMed Resources Logout
Select a Clinic:
--select a clinic--
Test Hospital
Test Report Hospital
Testing Site
Filter History
Upload Excel file:
Browse...
Upload
UPLOAD HISTORY
Clinic Name | Uploaded By | Uploaded On | File Name | Original Count | Min WO Date | Max WO Date | WO Date Overlapped | Status
Testing Site | | 4/4/2018 1:18:54 PM | FDA_CMMS_U | 6 | 02/22/1999 | 11/30/2013 | Yes | Success
Testing Site | | 4/4/2018 1:18:17 PM | FDA_CMMS_U | 0 | | | No | Fail
Testing Site | | 4/4/2018 1:15:26 PM | FDA_CMMS_U | 0 | | | No | Fail
Testing Site | | 4/4/2018 1:08:29 PM | FDA_CMMS_U | 6 | 02/22/1999 | 11/30/2013 | Yes | Success
Test Hospital | | 10/27/2017 4:08:47 PM | FDA_CMMS_U | 8 | 02/22/1999 | 11/30/2013 | No | Success
Test Hospital | | 10/27/2017 4:05:51 PM | FDA_CMMS_U | 0 | | | No | Fail
Test Hospital | | 10/27/2017 4:05:24 PM | FDA_CMMS_U | 0 | | | No | Fail
Test Hospital | | 3/11/2016 5:03:41 PM | FDA_CMMS_U | 0 | | | No | Fail

MedSun Medical Product Safety Network

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Browse/Edit Add Report Analysis Messages Options BioMed Resources Logout

Biomed File Upload

Clinic:	Testing Site
File Name:	FDA_CMMS_Upload_TemplateTestingSite4.xlsx
	Uploaded by *on 4/25/2019 10:45:49 AM*
Original Record Count:	6
Upload Status:	Success
WO Start:	
WO End:	

Export Results to Excel

UPLOAD HISTORY DETAILS

Overlapped	Record ID	Device Type	Manufacturer	Model	Serial Number	UDI	WO Opened Date	WO Type Code	WO Problem Code	WO Problem Descriptio
No	563593	microwave	Ohmeda	6600-0333-901	HCDD00364	UDI1-Col6-Col5	2/22/2018	RPR	PC1	Missing screws
No	563594	Incubator	Ohmeda	6600-0333-901	HCDD00365	UDI2-Col6-Col5	5/1/2018	RPR	PC2	Physical Damage
No	563595	Incubator	GE Medical Systems	PRO 200	010M0119022		11/30/2018	RPR		Monitor does not turn on.
No	563596	Incubator	GE Medical Systems	PRO 400 V1 Nellcor	000M2999067		12/20/2018	RPR		"Broken"
No	563597	dehydrator	TRP	T100000	L100			562390898		Error
No	563598	weighing machine	Airshields	TI1000000	U100		1/1/2018	89997986		Will not run on battery.

MedSun Medical Product Safety Network

Biomed

FDA U.S. FOOD & DRUG ADMINISTRATION

Home | Browse/Edit | Add Report | Analysis | Messages | Options | BioMed | Resources | Logout

The file you are attempting to upload (FDA_CMMS_Upload_Template.xlsx) has column header information that does not match the system's configuration for Testing Site.

For Column A : the expected column header is OTHER5, the actual column header is INFANT0104.

For Column B : the expected column header is MANUFACTURER_NAME, the actual column header is OHMEDA.

For Column C : the expected column header is MODEL_NAME_NBR, the actual column header is 6600-0333-901.

For Column D : the expected column header is SERIAL_NUMBER, the actual column header is HCDD00364.

For Column E : the expected column header is DATE_WO_OPENED, the actual column header is UDI1.

For Column F : the expected column header is UDI, the actual column header is 7/18/2011 3:20:50 PM.

For Column G : the expected column header is WO_TYPE_CODE, the actual column header is RPR.

For Column H : the expected column header is WO_PROBLEM_CODE, the actual column header is WPO1.

For Column I : the expected column header is WO_PROBLEM_DESC, the actual column header is MISSING SCREWS.

For Column J : the expected column header is WO_REPAIR_DESC, the actual column header is (TC 7/18/2011, JRS) SCREWS STRIPPED WHEN TECH CHANGED BATTERIES..

For Column K : the expected column header is OTHER1, the actual column header is .

For Column L : the expected column header is OTHER2, the actual column header is XLSX FILE.

For Column M : the expected column header is OTHER3, the actual column header is .

For Column N : the expected column header is OTHER4, the actual column header is .

For Column O : the expected column header is DEVICE_TYPE, the actual column header is EMILY OTHER5.

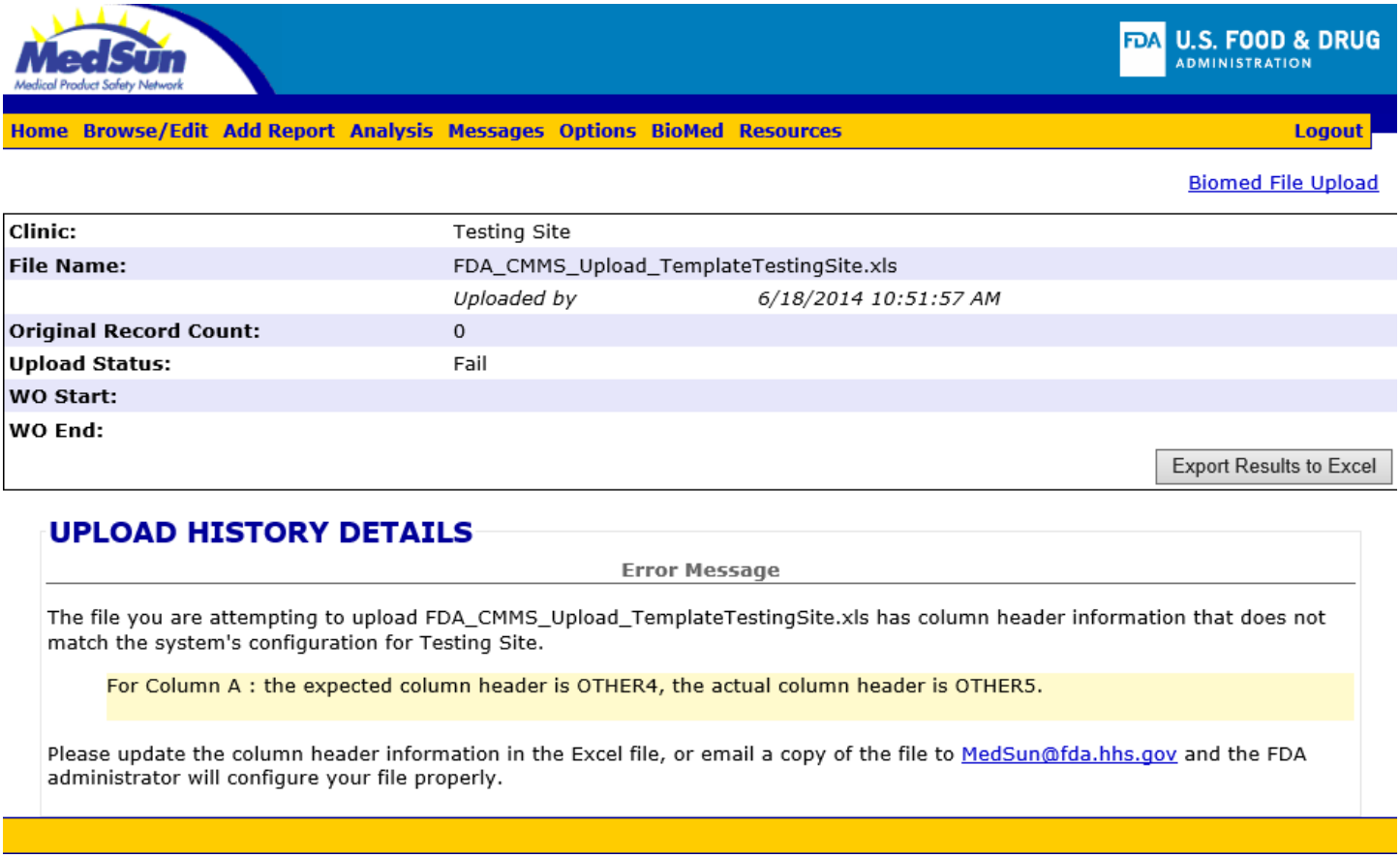
Please update the column header information in the Excel file, or email a copy of the file to MedSun@fda.hhs.gov and the FDA administrator will configure your file properly.

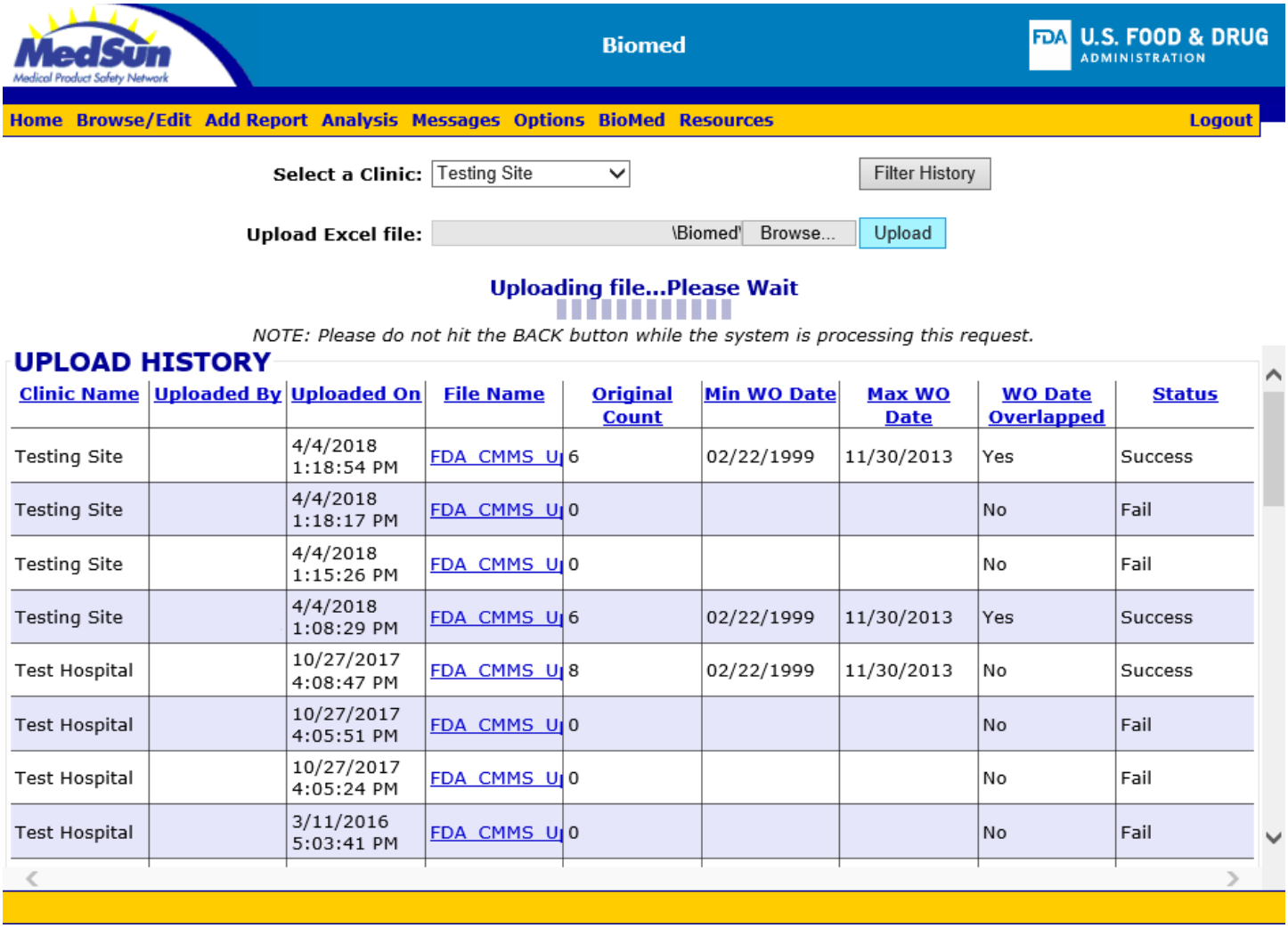
Select a Clinic: Testing Site Filter History

Upload Excel file: Browse... Upload

UPLOAD HISTORY

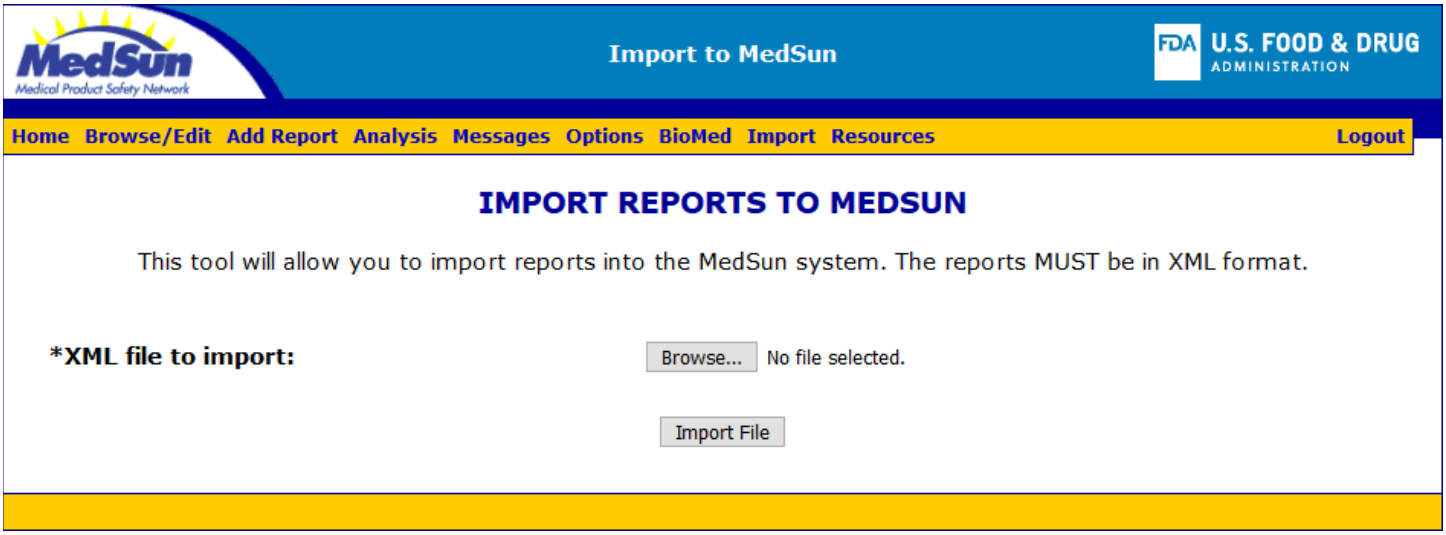
Clinic Name	Uploaded By	Uploaded On	File Name	Original Count	Min WO Date	Max WO Date	WO Date Overlapped	Status
Testing Site	Jose Estronza	4/25/2019 10:26:25 AM	FDA_CMMS_Uploa	0			No	Fail
Testing Site	Jose Estronza Toro	4/4/2018 1:18:54 PM	FDA_CMMS_Uploa	6	02/22/1999	11/30/2013	Yes	Success
Testing Site	Jose Estronza-Toro	4/4/2018 1:18:17 PM	FDA_CMMS_Uploa	0			No	Fail
Testing Site	Jose Estronza Toro	4/4/2018 1:15:26 PM	FDA_CMMS_Uploa	0			No	Fail
Testing Site	Jose Estronza-Toro	4/4/2018 1:08:29 PM	FDA_CMMS_Uploa	6	02/22/1999	11/30/2013	Yes	Success
Testing Site	Emily Zhou	1/14/2015 10:16:37 AM	FDA_CMMS_Uploa	0			No	Fail
Testing Site	Sudeshna Mandal	6/18/2014 12:21:11 PM	FDA_CMMS_Uploa	8	02/22/1999	11/30/2013	Yes	Success
Testing Site	Sudeshna Mandal	6/18/2014 12:20:57 PM	FDA_CMMS_Uploa	8	02/22/1999	11/30/2013	Yes	Success


MedSun
Medical Product Safety Network
FDA U.S. FOOD & DRUG ADMINISTRATION
Home Browse/Edit Add Report Analysis Messages Options BioMed Resources Logout
Biomed File Upload
Clinic: Testing Site
File Name: FDA_CMMS_Upload_TemplateTestingSite.xls
Uploaded by 6/18/2014 10:51:57 AM
Original Record Count: 0
Upload Status: Fail
WO Start:
WO End:
Export Results to Excel
UPLOAD HISTORY DETAILS
Error Message
The file you are attempting to upload FDA_CMMS_Upload_TemplateTestingSite.xls has column header information that does not match the system's configuration for Testing Site.
For Column A : the expected column header is OTHER4, the actual column header is OTHER5.
Please update the column header information in the Excel file, or email a copy of the file to MedSun@fda.hhs.gov and the FDA administrator will configure your file properly.

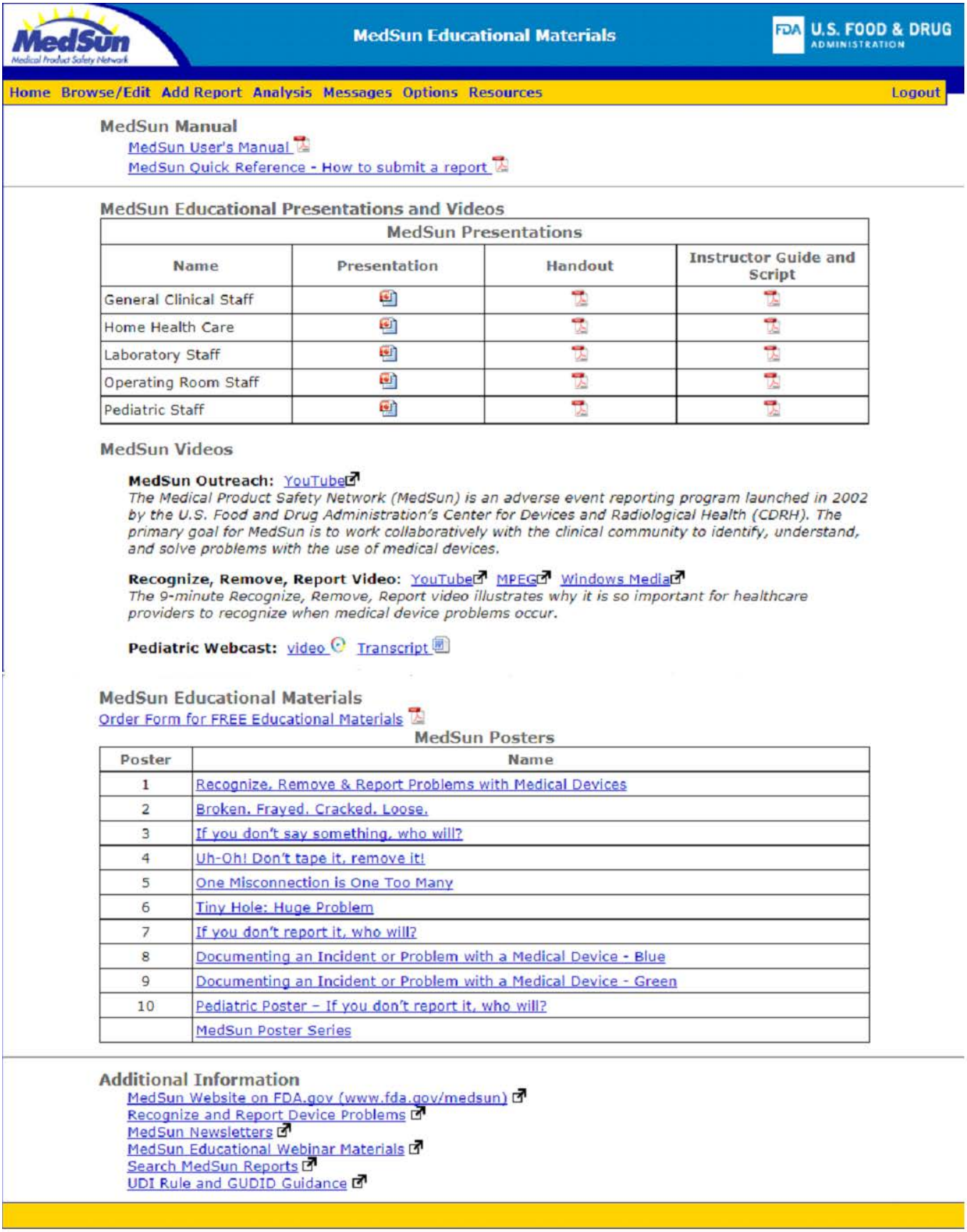


Import

Import



Resources



MedSun Educational Materials

U.S. FOOD & DRUG ADMINISTRATION

Home Browse/Edit Add Report Analysis Messages Options Resources Logout

MedSun Manual

MedSun User's Manual

MedSun Quick Reference - How to submit a report

MedSun Educational Presentations and Videos

MedSun Presentations			
Name	Presentation	Handout	Instructor Guide and Script
General Clinical Staff			
Home Health Care			
Laboratory Staff			
Operating Room Staff			
Pediatric Staff			

MedSun Videos

MedSun Outreach: YouTube

The Medical Product Safety Network (MedSun) is an adverse event reporting program launched in 2002 by the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices.

Recognize, Remove, Report Video: YouTube MPEG Windows Media

The 9-minute Recognize, Remove, Report video illustrates why it is so important for healthcare providers to recognize when medical device problems occur.

Pediatric Webcast: video Transcript

MedSun Educational Materials

Order Form for FREE Educational Materials

MedSun Posters

Poster	Name
1	Recognize, Remove & Report Problems with Medical Devices
2	Broken, Frayed, Cracked, Loose.
3	If you don't say something, who will?
4	Uh-Oh! Don't tape it, remove it!
5	One Misconnection is One Too Many
6	Tiny Hole: Huge Problem
7	If you don't report it, who will?
8	Documenting an Incident or Problem with a Medical Device - Blue
9	Documenting an Incident or Problem with a Medical Device - Green
10	Pediatric Poster – If you don't report it, who will?
	MedSun Poster Series

Additional Information

MedSun Website on FDA.gov (www.fda.gov/medsun)

Recognize and Report Device Problems

MedSun Newsletters

MedSun Educational Webinar Materials

Search MedSun Reports

UDI Rule and GUDID Guidance