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See OMB statement on reverse.

**U.S. Department of Health and Human Services**
Food and Drug Administration

# MEDWATCH

**FORM FDA 3500A (6/10)**

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

Page 1 of ____

| Mfr Report # |
|---|
| UF/Importer Report # |
| **FDA Use Only** |

PLEASE TYPE OR USE BLACK INK

## A. PATIENT INFORMATION

| 1. Patient Identifier | 2. Age at Time of Event: or Date of Birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| In confidence | | ☐ Female ☐ Male | ____ lbs or ____ kgs |

## B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ **Adverse Event** and/or ☐ **Product Problem** *(e.g., defects/malfunctions)*

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*

☐ Death: _____ *(mm/dd/yyyy)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

| 3. Date of Event *(mm/dd/yyyy)* | 4. Date of This Report *(mm/dd/yyyy)* |
|---|---|
| | |

5. **Describe Event or Problem**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

**Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.**

## C. SUSPECT PRODUCT(S)

1. **Name** *(Give labeled strength & mfr/labeler)*
#1
#2

| 2. Dose, Frequency & Route Used | 3. Therapy Dates *(If unknown, give duration from/to (or best estimate)* |
|---|---|
| #1 | #1 |
| #2 | #2 |

| 4. Diagnosis for Use *(Indication)* | 5. Event Abated After Use Stopped or Dose Reduced? |
|---|---|
| #1 | #1 ☐ Yes ☐ No ☐ Doesn't Apply |
| #2 | #2 ☐ Yes ☐ No ☐ Doesn't Apply |

| 6. Lot # | 7. Exp. Date | 8. Event Reappeared After Reintroduction? |
|---|---|---|
| #1 | #1 | #1 ☐ Yes ☐ No ☐ Doesn't Apply |
| #2 | #2 | #2 ☐ Yes ☐ No ☐ Doesn't Apply |

9. **NDC# or Unique ID**

10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

## D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

| 2a. Common Device Name | 2b. Procode |
|---|---|
| | |

3. **Manufacturer Name, City and State**

| 4. Model # | Lot # | 5. Operator of Device |
|---|---|---|
| Catalog # | Expiration Date *(mm/dd/yyyy)* | ☐ Health Professional ☐ Lay User/Patient ☐ Other: |
| Serial # | Unique ID (UDI) # | |

| 6. If Implanted, Give Date *(mm/dd/yyyy)* | 7. If Explanted, Give Date *(mm/dd/yyyy)* |
|---|---|
| | |

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?**
☐ Yes ☐ No

9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

10. **Device Available for Evaluation?** *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

## E. INITIAL REPORTER

| 1. Name and Address | Phone # |
|---|---|
| | Email Address: |

| 2. Health Professional? | 3. Occupation | 4. Initial Reporter Also Sent Report to FDA |
|---|---|---|
| ☐ Yes ☐ No | | ☐ Yes ☐ No ☐ Unk. |

# MEDWATCH

**FORM FDA 3500A (6/10)** *(continued)*



FDA USE ONLY

## F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

1. **Check One** ☐ User Facility ☐ Importer
2. **UF/Importer Report Number**
3. **User Facility or Importer Name/Address**
4. **Contact Person**
5. **Phone Number**
6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*
7. **Type of Report** ☐ Initial ☐ Follow-up # _____
8. **Date of This Report** *(mm/dd/yyyy)*
9. **Approximate Age of Device**
10. **Event Problem Codes** *(Refer to coding manual)*
   Patient Code ___ – ___ – ___
   Device Code ___ – ___ – ___
11. **Report Sent to FDA?** ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
12. **Location Where Event Occurred** ☐ Hospital ☐ Home ☐ Nursing Home ☐ Outpatient Treatment Facility ☐ Outpatient Diagnostic Facility ☐ Ambulatory Surgical Facility ☐ Other: _____ *(Specify)*
13. **Report Sent to Manufacturer?** ☐ Yes _____ *(mm/dd/yyyy)* ☐ No
14. **Manufacturer Name/Address**

## G. ALL MANUFACTURERS

1. **Contact Office - Name/Address** ***(and Manufacturing Site for Devices)***
   **Email Address**
2. **Phone Number**
3. **Report Source** *(Check all that apply)* ☐ Foreign ☐ Study ☐ Literature ☐ Consumer ☐ Health Professional ☐ User Facility ☐ Company Representative ☐ Distributor ☐ Other: _____
4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
5. (A)NDA # _____ IND # _____ BLA # _____ PMA/510(k) # _____ Combination Product ☐ Yes Pre-1938 ☐ Yes OTC Product ☐ Yes
6. **If IND, Give Protocol #**
7. **Type of Report** *(Check all that apply)* ☐ 5-day ☐ 30-day ☐ 7-day ☐ Periodic ☐ 10-day ☐ Initial ☐ 15-day ☐ Follow-up # ____
8. **Adverse Event Term(s)**
9. **Manufacturer Report Number**

## H. DEVICE MANUFACTURERS ONLY

1. **Type of Reportable Event** ☐ Death ☐ Serious Injury ☐ Malfunction ☒ Other
2. **If Follow-up, What Type?** ☐ Correction ☐ Additional Information ☐ Response to FDA Request ☐ Device Evaluation
3. **Device Evaluated by Manufacturer?** ☐ Not Returned to Manufacturer ☐ Yes ☐ Evaluation Summary Attached ☐ No *(Attach page to explain why not)* or provide code: _____
4. **Device Manufacture Date** *(mm/yyyy)*
5. **Labeled for Single Use?** ☐ Yes ☐ No
6. **Evaluation Codes** *(Refer to coding manual)*
   Patient Code ___ – ___ – ___
   Device Code ___ – ___ – ___
   Method ___ – ___ – ___ – ___
   Results ___ – ___ – ___ – ___
   Conclusions ___ – ___ – ___ – ___
7. **If Remedial Action Initiated, Check Type** ☐ Recall ☐ Repair ☐ Replace ☐ Relabeling ☐ Notification ☐ Inspection ☐ Patient Monitoring ☐ Modification/Adjustment ☐ Other: _____
8. **Usage of Device** ☐ Initial Use of Device ☐ Reuse ☐ Unknown
9. **If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:**
10. ☐ **Additional Manufacturer Narrative** and / or 11. ☐ **Corrected Data**

The public reporting burden for this collection of information has been estimated to average 66 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 Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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