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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 (2/13)

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

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. **Patient Identifier** — In confidence
2. **Age at Time of Event:** or **Date of Birth:** _____
3. **Sex** ☐ Female ☐ Male
4. **Weight** _____ 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)*
   - ☐ Disability or Permanent Damage
   - ☐ Life-threatening
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Hospitalization - initial or prolonged
   - ☐ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

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

5. **Describe Event or Problem**

(Continue on page 3)

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

(Continue on page 3)

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

(Continue on page 3)

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**
   #1
   #2
3. **Therapy Dates** *(If unknown, give duration) from/to (or best estimate)*
   #1
   #2
4. **Diagnosis for Use** *(Indication)*
   #1
   #2
5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
6. **Lot #**
   #1
   #2
7. **Exp. Date**
   #1
   #2
8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply
9. **NDC# or Unique ID**
10. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event)*

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name**
2b. **Procode**
3. **Manufacturer Name, City and State**
4. **Model #** **Lot #**
   Catalog # **Expiration Date** *(mm/dd/yyyy)*
   Serial # **Unique Identifier (UDI) #**
5. **Operator of Device**
   ☐ Health Professional
   ☐ Lay User/Patient
   ☐ Other: _____
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)*

(Continue on page 3)

E. INITIAL REPORTER

1. **Name and Address**

Phone #

Email Address

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

MedWatch

FORM FDA 3500A (2/13) *(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 (and Manufacturing Site for Devices)**
   Name
   Address
   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
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. **Event Problem and Evaluation Codes** *(Refer to coding manual)*
   Patient Code ___ - ___ - ___
   Device Code ___ - ___ - ___
   Method ___ - ___ - ___ - ___
   Results ___ - ___ - ___ - ___
   Conclusions ___ - ___ - ___ - ___
7. **If Remedial Action Initiated, Check Type**
   ☐ Recall ☐ Notification
   ☐ Repair ☐ Inspection
   ☐ Replace ☐ Patient Monitoring
   ☐ Relabeling ☐ 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**

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(CONTINUATION PAGE)

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MEDWATCH

FORM FDA 3500A (2/13) *(continued)*

Back to Item B.5

B.5. **Describe Event or Problem** *(continued)*

Back to Item B.6

B.6. **Relevant Tests/Laboratory Data, Including Dates** *(continued)*

Back to Item B.7

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

Back to Item C.10 Back to Item D.11

Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)*

Other Remarks