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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 (10/05)

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

Page ____ of ____

Mfr Report #

UF/Importer Report #

FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. **Patient Identifier** ID
In confidence

2. **Date of Birth:** BIRTHDATE

3. **Sex** SAESEX
☐ Female ☐ Male

4. **Weight** SAEWGT
____ 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: DTHDATE *(mm/dd/yyyy)* DTH
☐ Life-threatening LIFETHR
☐ Hospitalization - initial or prolonged HOSP
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices) RINT
☐ Disability or Permanent Damage DISABLE
☐ Congenital Anomaly/Birth Defect BDEFECT
☐ Other Serious (Important Medical Events) OTHSAE

3. **Date of Event** *(mm/dd/yyyy)* AEM/AED/AEY

4. **Date of This Report** *(mm/dd/yyyy)* MWRM/MWRD/MWRY

5. **Describe Event or Problem** SAEDESC

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

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

Was AE serious in nature? SAENAT
Was AE related to medicinal product? SAEMED
Was AE unexpected? UNEXP

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 SMED1
#2 SMED2

2. **Dose, Frequency & Route Used**
#1 SMDOSE1
#2 SMDOSE2

3. **Therapy Dates** *(If unknown, give duration from/to (or best estimate))*
#1 SMST1M/D/Y-SMSP1M/D/Y
#2 SMST2M/D/Y-SMSP2M/D/Y

4. **Diagnosis for Use** *(Indication)*
#1 SMIND1
#2 SMIND2

5. **Event Abated After Use Stopped or Dose Reduced?** ABAT1
#1 ☐ Yes ☐ No ☐ Doesn't Apply
ABAT2
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. **Lot #**
#1 LOT1
#2 LOT2

7. **Exp. Date**
#1 EXPDATE1
#2 EXPDATE2

8. **Event Reappeared After Reintroduction?** RAPP1
#1 ☐ Yes ☐ No ☐ Doesn't Apply
RAPP2
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC# or Unique ID** NDC

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

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Common Device Name**

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 # | **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)*

E. INITIAL REPORTER

1. **Name and Address** | **Phone #**

Was this form reviewed by a HBRN physician investigator? IRREV

2. **Health Professional?** ☑ Yes ☐ No

3. **Occupation** IROCC

4. **Initial Reporter Also Sent Report to FDA** ☐ Yes ☑ No ☐ Unk.