U.S. Department of Health and Human Services

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

1. **Patient Identifier**	2. **Age at Time of Event:**	3. **Sex**	4. **Weight**
In confidence	or ____ **Date of Birth:**	☐ 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: ____ *(mo/day/yr)*
☐ Life-threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Anomaly
☐ Required Intervention to Prevent Permanent Impairment/Damage
☐ Other: ____

3. **Date of Event** *(mo/day/year)*

4. **Date of This Report** *(mo/day/year)*

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.)*

C. SUSPECT MEDICATION(S)

1. **Name** *(Give labeled strength & mfr/labeler, if known)*

#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 #** *(if known)*

#1

#2

7. **Exp. Date** *(if known)*

#1

#2

8. **Event Reappeared After Reintroduction?**

#1 ☐ Yes ☐ No ☐ Doesn't Apply

#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC#** *(For product problems only)*

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

D. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2. **Type of Device**

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

4. **Model #**	**Lot #**	5. **Operator of Device**
Catalog #	**Expiration Date** *(mo/day/yr)*	☐ Health Professional ☐ Lay User/Patient
Serial #	**Other #**	☐ Other:

6. **If Implanted, Give Date** *(mo/day/yr)*

7. **If Explanted, Give Date** *(mo/day/yr)*

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: ____ *(mo/day/yr)*

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

E. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Phone #

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

3. **Occupation**

4. **Also Reported to:** ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 *-or-* **FAX to:** 1-800-FDA-0178

FORM FDA 3500 (12/03) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**