

**MEDWATCH**  
FDA eSubmitter Generated Form 3500A

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

<b>Mfr Report #:</b>	1234567-2023-00001
<b>UF/Importer Report #:</b>	
<b>Form Code:</b>	
<b>Exemption Number:</b>	

**A. PATIENT INFORMATION**

<b>1. Patient Identifier</b> <i>(In confidence)</i>	<b>2. Age at Time of Event, Date of Birth</b>	<b>3a. Sex</b>	<b>3b. Gender</b>	<b>4. Weight</b>
<b>5. Ethnicity</b> ( ) Hispanic/Latino ( ) Not Hispanic/Latino				
<b>6. Race</b> [ ] Asian [ ] White [ ] American Indian or Alaskan Native [ ] Native Hawaiian or Other Pacific Islander [ ] Black or African American				

**B. ADVERSE EVENT OR PRODUCT PROBLEM**

<b>1.</b> [ ] Adverse Event <b>and/or</b> [ ] Product Problem <i>(e.g., defects/malfunctions)</i>	
<b>2. Outcomes Attributed to Adverse Event</b> <i>(Checked all that apply)</i> [ ] Death [ ] Disability or Permanent Damage [ ] Life-threatening [ ] Congenital Anomaly/Birth Defect [ ] Hospitalization (initial or prolonged) [ ] Other Serious or Important Medical Events [ ] Required Intervention to Prevent Permanent Impairment/Damage	
<b>3. Date of Event</b> <i>(dd-mmm-yyyy)</i>	<b>4. Date of this Report</b> <i>(dd-mmm-yyyy)</i>
<b>5. Describe Event or Problem</b> Additional event narrative.	
<b>6. Relevant Tests/Laboratory Data, Including Dates</b>	
<b>7. Other Relevant History, Including Preexisting Medical Conditions</b> <i>(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)</i>	

**C. SUSPECT PRODUCT(S)**

**D. SUSPECT MEDICAL DEVICE**

<b>1. Brand Name</b>	<b>2. Common Device Name</b>	
<b>3. Manufacturer Name, City and State</b>	<b>4. Model #</b>	<b>Catalog #</b>
	<b>Serial #</b>	<b>Lot #</b>
	<b>Expiration Date</b> <i>(dd-mmm-yyyy)</i>	
	<b>Unique Identifier (UDI) #</b>	
<b>5. Operator of Device</b>	<b>6a. If Implanted, Give Date</b> <i>(dd-mmm-yyyy)</i>	<b>6b. If Explanted, Give Date</b> <i>(dd-mmm-yyyy)</i>
<b>7a. Is this a Single-Use Device that was reprocessed and Reused on a Patient?</b> ( ) Yes ( ) No	<b>7b. If yes, Enter Name and Address of Reprocessor</b>	
<b>8. Was this device serviced by a third party?</b> ( ) Yes ( ) No ( ) Unknown	<b>9. Device Available for Evaluation?</b> <i>(Do not send to FDA)</i> ( ) Yes ( ) No [ ] Returned to Manufacturer	
<b>10. ConComitant Medical Products and Therapy Dates</b> <i>(Excludes treatment of event)</i>		

**E. INITIAL REPORTER**

<b>1. Name and Address</b>	<b>2. Health Professional?</b> ( ) Yes ( ) No
	<b>3. Occupation</b>

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<b>4. Initial Reporter Also Sent Report to FDA?</b> ( ) Yes ( ) No ( ) Unk	

F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)	
<b>1. User Facility or Importer</b> ( ) User Facility ( ) Importer	<b>2. User Facility/Importer Report Number</b>
<b>3, 4, and 5. User Facility or Importer Name/Address, Contact Person, and Phone Number</b>	<b>6. Date UF/Importer Became Aware of Event (dd-mmm-yyyy)</b>
	<b>7. Type of Report</b> ( ) Initial ( ) Follow-up
	<b>8. Date of This Report (dd-mmm-yyyy)</b> <b>9. Approximate Age of Device</b>
<b>10. Adverse Event Problem (Refer to coding manual)</b> Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code:	<b>14. Manufacturer Name/Address</b>
<b>11. Report Sent to FDA?</b> ( ) Yes ( ) No	
<b>12. Location Where Event Occurred</b>	
<b>13. Report Sent to Manufacturer?</b> ( ) Yes ( ) No	

G. ALL MANUFACTURERS	
<b>1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility</b>	<b>1. Contact Office - Manufacturing Site</b>
<b>2. Report Source (Check all that apply)</b> [ ] Foreign                      [ ] Health Professional [ ] Study                         [ ] User Facility [ ] Literature                    [ ] Company Representative [ ] Consumer                    [ ] Distributor/Importer [ ] Other	<b>3. Date Received by Manufacturer (dd-mmm-yyyy)</b>
	<b>4. Premarket Identification</b> PMA/510(k): [ ] Combination Product      Device BLA:
	<b>5. If IND/PreANDA, Give Protocol #</b>
<b>6. Type of Report</b> [ ] 5-day                         [ ] Periodic [ ] 7-day                         [ ] Initial [ ] 15-day                        [x] Follow-up #: 1 [x] 30-day	<b>7. Adverse Event Term(s)</b>
	<b>8. Manufacturer Report Number</b> 1234567-2023-00001

H. DEVICE MANUFACTURERS ONLY		
<b>1. Type of Reportable Event</b> ( ) Death ( ) Serious Injury ( ) Malfunction [ ] Summary Report No. of Events Summarized:	<b>2. If Follow-up, What Type?</b> [x] Correction [x] Additional Information [ ] Response to FDA Request [ ] Device Evaluation	<b>3. Device Evaluated by Manufacturer?</b> ( ) Yes ( ) No
<b>4. Device Manufacture Date (dd-mmm-yyyy)</b>	<b>6. Adverse Event Problem (Refer to coding manual)</b> Health Effect - Clinical Code: Health Effect - Impact Code: Medical Device Problem Code: Component Code: Type of Investigation: Investigation Findings:	
<b>5. Labeled for Single Use?</b> ( ) Yes ( ) No		

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		Investigation Conclusions:	
<b>7. If Remedial Action initiated, Check Type</b> <input type="checkbox"/> Recall <input type="checkbox"/> Repair <input type="checkbox"/> Replace <input type="checkbox"/> Relabeling <input type="checkbox"/> Other		<b>8. Usage of Device</b> <input type="checkbox"/> Initial Use of Device <input type="checkbox"/> Reuse <input type="checkbox"/> Unknown	
		<b>9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number</b>  <b>10. Related Report Numbers:</b>	
<b>11. Additional Manufacturer Narrative</b> Additional follow-up manufacturer narrative.			
<b>File Attachments</b>			
No files attached.			