#### DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

## MEDICAL DEVICE REPORTING ANNUAL USER FACILITY REPORT

CDRH Medical Device Reporting P.O. Box 3002 Rockville, MD 20847-3002

# PART 1 - COVER SHEET

If MDR reports were not submitted to either the FDA or a device manufacturer during this reporting period, DO NOT submit an annual report.

### PART 1 INSTRUCTIONS

Complete one copy of the following information as a cover page for the annual report and return to the address listed above. This report should NOT include reports that are not required but have been submitted voluntarily.

1. REPORT PERIOD	2. USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER)
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3. USER FACILITY INFORMATION	4. USER FACILITY CONTACT INFORMATION
a. Name	a. Name
b. Street Address	b. Street Address
c. City d. State e. ZIP Code	c. City d. State e. ZIP Code
f. Country/Postal Code (if not U.S.)	f. Country/Postal Code (if not U.S.)
	g. Telephone Number (Include area code and extension)
5. TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED	
a. Lowest Report Number	•
(HCFA or FDA Provided No.)	(Year) (Sequence No.)
a. Lowest Report Number	-
	(Year) (Sequence No.)
For each report in the range of report numbers listed above, attach a	completed copy of Part 2 of this form, or a photocopy of the completed
	r the manufacturer. In addition, attach a sheet listing report numbers in the
above range that are not included in this report and explain why.	
6. SIGNATURE OF CONTACT	7. DATE OF REPORT
Paperwork Reduction Act Statement	
Public reporting burden for this collection of information is estimated to average 1 hours per response, including the time for reviewing instructions,	
searching existing data sources, gathering and maintaining the data needed, and completing 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:	
Center for Devices and Radiological Health	
Office of Surveillance and Biometrics Division of Surveillance Systems, RSMB, HFZ-533	
1350 Piccard Drive	
Rockville, MD 20850 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control	
An agency may not conduct or sponsor, and a person is not required to respond to, a conection of information unless it displays a currently valid OMD control number	

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#### **PART 2 - SUMMARY OF EVENT**

#### PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the calendar year covered by this Annual Report.

1. USER FACILITY EVENT REPORT NUMBER

(HCFA or FDA Provided No.) (Year) (Sequence No.)

2. WHERE WAS REPORT SUBMITTED? (Check all that apply)

FDA Manufacturer Distributor

Other \_\_\_\_\_

3. MANUFACTURER INFORMATION	4. DEVICE INFORMATION
a. Name	a. Brand Name
	b. Common Name
b. Street Address	
	c. Model Number
c. City d. State e. ZIP Code	d. Serial Number
	e. Lot Number
f. Country/Postal Code (if not U.S.)	
	f. Catalog Number
5. BRIEF DESCRIPTION OF EVENT	