DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

MEDICAL DEVICE REPORTING ANNUAL USER FACILITY REPORT

OMB: 0910-0437
Exp. Date: 8/31/2015

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)
JAN - DEC __ __ __ __ (Y Y Y Y)	

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.)

b. Highest Report Number __ __ __ __ __ __ __ __ __ __ - __ __ __ __ - __ __ __ __
(HCFA or FDA Provided No.) (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 MedWatch FDA Form 3500A for the event that was sent to FDA and/or 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
	__ __/__ __/__ __ __ __ (M M D D Y Y Y Y)

This section applies only to the requirements of the Paperwork Reduction Act of 1995.

*****DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*****

The public reporting burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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 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