DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CDRH MEDICAL DEVICE REPORTING
P.O. BOX 3002
ROCKVILLE, MD 20847-3002

FORM APPROVED: OMB No. 0910-0059
EXPIRES: 02/28/99

MEDICAL DEVICE REPORTING - ANNUAL CERTIFICATION

PART 1

NOTE: This form is authorized by Section 519 of the Food, Drug and Cosmetic Act *(21 U.S.C. 360)*. Failure to report this information is a violation of Section 301(p) of the Act *(21 U.S.C. 331(p))*. Persons who violate this provision may, if convicted, be subject to a fine or imprisonment or both. The submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2) *(21 U.S.C. 331(q)(2))* and may be a violation of 18 U.S.C. 1001.

INSTRUCTIONS: Please complete Part 1, then complete and sign Part 2 in order to comply with the certification requirement. The certification period and FDA registration number shown on Part 1 must be repeated on each attached Part 2. More than one Part 2 must be completed if the number of entries exceeds the number of rows in Part 2, item 3. Return all parts of this report to the address listed above.

1. This Certification Covers the Period

__ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y) To __ __ / __ __ / __ __ __ __ (M M D D Y Y Y Y)

2. REPORTING SITE INFORMATION	3. CERTIFICATION INFORMATION
a. FDA Registration Number	a. Name of Person Completing Certification
b. Firm Name	b. Title
c. Street Address	c. Street Address
d. City e. State f. ZIP Code	d. City e. State f. ZIP Code
g. Country/Postal Code *(if not U.S.)*	g. Telephone Number *(Include area code and, if applicable, extension)*
h. Type of Firm *(Check all that apply)* ☐ Manufacturer ☐ Distributor ☐ U.S. Agent of a Foreign Manufacturer	

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please DO NOT RETURN this form to this address.)

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

PAGE ____ OF ____

INSTRUCTIONS: Refer to Part 1 of this form to complete items 1. and 2. below. Then complete the information in item 3. below for each appropriate site that this certification covers, including the number of MDR reportable events that have been received and submitted to FDA. If any or all the sites have had **NO** reportable events, enter a zero in the appropriate column. Use additional Part 2 pages if the number of entries exceeds the number of available rows. Return all parts of this form to the address listed at the **top** of Part 1.

1. CERTIFICATION PERIOD *(From Part 1, item 1.)*

__ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y) To __ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

2. FDA REGISTRATION NUMBER *(From Part 1, item 2.a.)*

3. MEDICAL DEVICE REPORTS SUBMITTED DURING THIS CERTIFICATION PERIOD

MANUFACTURING SITE REGISTRATION NUMBER*	MANUFACTURING SITE NAME*	MANUFACTURING SITE ADDRESS* CITY / STATE / ZIP OR POSTAL CODE / COUNTRY	MANUFACTURER	DISTRIBUTOR
*Distributors use reporting site registration number.	*Distributors use reporting site name.	*Distributors use reporting site address.	No. of Reports	No. of Reports

4. CERTIFICATION

I certify that, to the best of my knowledge, the firm(s) listed in item 3. above either submitted the MDR Reports indicated above during the stated reporting period and that this number represents the submissions for all appropriately reportable MDR events or that the firm listed above did not receive any MDR reportable events during this time period. I also certify that, to the best of my knowledge, the statements and information presented in this submission are truthful and accurate.

WARNING: Any false, fictitious, or fraudulent statement or information presented in this submission could subject you to criminal prosecution, administrative penalties, or both.

5. SIGNATURE OF CERTIFYING OFFICIAL

6. DATE OF SIGNATURE

__ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)