

**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

**FOR FDA USE ONLY**

**MEDICAL DEVICE REPORTING  
 BASELINE REPORT**

**PART 1**

**INSTRUCTIONS**

Part 1 is a cover sheet for single or multiple copies of Part 2. The FDA Registration Number, (item 2.b.) and the Date of Baseline Report, (item 7.) must be provided on each attached Part 2. Return this form to the address listed above.

**1. TYPE OF BASELINE REPORT**

Initial

Annual Update

**2. FIRM INFORMATION (Reporting Site)**

a. Firm Name	
b. FDA Registration Number (Reporting Site)	
c. Street Address	
d. City	
e. State	f. ZIP Code
g. Country/Postal code (if not U.S.)	

**3. MANUFACTURER CONTACT INFORMATION**

a. Name	
b. Title	
c. Street Address	
d. City	
e. State	f. ZIP Code
g. Telephone Number (Include area code and extension) (       )	

**4. NUMBER OF "Baseline Reports - Part 2" attached**

**5. ARE YOU THE U.S. AGENT FOR A FOREIGN MANUFACTURER PER 21 CFR 803, 807?**

YES                       NO

**6. SIGNATURE**

**7. DATE**

    — — / — — / — — — —  
     M M / D D / Y Y Y Y

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 (0910-0056)  
 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.

## MEDICAL DEVICE REPORTING - BASELINE REPORT

INITIAL       ANNUAL UPDATE

### PART 2

**INSTRUCTIONS:** Complete ONE copy of the following information for EACH device model. If model is not used, select another identifier from the device's labeling. Refer to baseline instructions, separate from this form, for detailed guidance.

FDA REGISTRATION NUMBER \_\_\_\_\_  
*(Reporting Site)*

DATE OF BASELINE REPORT \_\_\_\_/\_\_\_\_/\_\_\_\_\_  
M M D D Y Y Y Y

**1. MANUFACTURING SITE(S) FOR THIS DEVICE**

a. FDA Registration Number (Manufacturing Site)	b. Firm Name (Manufacturing Site)

*Note: If more space is required attach additional Part 2 pages, providing items 1.a. & 1.b. Include the FDA reporting site registration number (Part 1, item 2.b.), the date (Part 1, item 7.), device brand name (Part 2, item 2.), and model (Part 2, item 4.) for a cross reference on each page.*

2. DEVICE BRAND NAME	3. DEVICE GENERIC NAME	4. DEVICE MODEL NUMBER
5. DEVICE CATALOG NUMBER	6. OTHER DEVICE IDENTIFIER	
7. FDA PRODUCT CODE (Refer to FDA Classification Names booklet.)	8. MANUFACTURER'S DEVICE FAMILY NAME	

**9. RELATED DEVICE IDENTIFICATION** *If this device, or a substantially similar device, was previously distributed with a different device identification, provide the following:*

a. Previous Device Identifier _____	b. Type of Identifier <input type="checkbox"/> Model <input type="checkbox"/> Catalog <input type="checkbox"/> Other _____	c. Date of Prior Baseline Report ____/____/_____ M M D D Y Y Y Y
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<p><b>10. BASIS FOR MARKETING</b></p> <p>a. 510 (k) ..... <input type="checkbox"/> Yes, Number _____ <input type="checkbox"/> No</p> <p>b. PMA ..... <input type="checkbox"/> Yes, Number _____ <input type="checkbox"/> No</p> <p>c. Preamendment ... <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>d. Transitional ..... <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>e. 510 (k) Exempt... <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p><b>11. DEVICE LIFE</b></p> <p>a. Shelf Life _____ months <input type="checkbox"/> N/A</p> <p>Is shelf life labeled? (Go to 11.b. if N/A) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>b. Expected Life _____ months <input type="checkbox"/> N/A <input type="checkbox"/> Not Established/Indefinite</p>
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12. DATE DEVICE FIRST MARKETED ____/____/_____ M M D D Y Y Y Y	13. DATE DEVICE CEASED BEING MARKETED (If applicable) ____/____/_____ M M D D Y Y Y Y	14. IS THE DEVICE THE SUBJECT OF AN APPROVED POST MARKET (522) STUDY? <input type="checkbox"/> Yes <input type="checkbox"/> No
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**15. NUMBERS OF THIS DEVICE**      Number

a. Manufactured in the last 12 months ... _____	<input type="checkbox"/> Actual <input type="checkbox"/> Estimated <input type="checkbox"/> Actual <input type="checkbox"/> Estimated	<i>NOTE: Attach a copy of the method used to estimate the numbers in 15.b./15.c. OR if the method has been submitted in a previous baseline report complete item 16. below.</i>
b. Distributed in the last 12 months ..... _____		
c. In current use ..... _____		

**16. IF THE METHOD USED TO ESTIMATE THE NUMBERS IN 15.b. and/or 15.c. ABOVE HAS BEEN SUBMITTED IN A PREVIOUS BASELINE REPORT, COMPLETE THE FOLLOWING:**

	<i>ID for device in prior baseline report</i>	<i>Date of previous baseline report</i>
Distribution Estimation Method _____	_____	____/____/_____ M M D D Y Y Y Y
Current Use Estimation Method _____	_____	____/____/_____ M M D D Y Y Y Y