

**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. 0910-0437  
 EXPIRES: 3/31/03

**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:

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 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 \_\_\_\_\_

DATE OF BASELINE

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

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

c. Date of Prior Baseline Report

 Model

 Catalog

 Other

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

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10. BASIS FOR MARKETING

 a. 510 (k)  Yes, Number \_\_\_\_\_  No

 b. PMA  Yes, Number \_\_\_\_\_  No

 c. Preamendment  Yes  No

 d. Transitional  Yes  No

 e. 510 (k) Exempt  Yes  No

11. DEVICE LIFE

 a. Shelf Life \_\_\_\_\_ months  N/A

 Is shelf life labeled? (Go to 11.b. if N/A)  Yes  No

 b. Expected Life \_\_\_\_\_ months  N/A  Not Established/Indefinite

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?

 Yes  No

15. NUMBERS OF THIS DEVICE

Number

a. Manufactured in the last 12 months .....

 b. Distributed in the last 12 months .....  Actual  Estimated

 c. In current use .....  Actual  Estimated

**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.

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:

ID for device in prior baseline report
Date of previous baseline

Distribution Estimation Method

\_\_\_\_\_

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

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Current Use Estimation Method

\_\_\_\_\_

\_\_\_\_ / \_\_\_\_ / \_\_\_\_

M M / D D / Y Y Y Y