DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DEVICE LISTING

Form Approved: OMB No. 0910-0387.
Expiration Date: March 31, 2005.

Complete and Return to:

Food and Drug Administration
Center for Devices and Radiological Health
Information Processing and Office Automation Branch (HFZ-308)
9200 Corporate Blvd.
Rockville, MD 20850-4015

Print

Clear Form

NOTE: This form is authorized by Section 510 of the Federal 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(g)(2) and may be a violation of 18 U.S.C. 1001.

1. DOCUMENT NUMBER

E

1a. PREVIOUS DOCUMENT NUMBER

2. REASON FOR SUBMISSION

- ☐ New Listing
- ☐ Update to Device Already Listed
- ☐ Discontinuing Product Line

3. REPORT DATE

MO.	DAY	YR.

4. OWNER / OPERATOR NUMBER

5. OWNER / OPERATOR NAME *(changes in owner/operator must be reported using form FDA 2891a or by letter)*

6. ADDRESS

a. NUMBER and STREET

b. CITY, STATE, ZIP CODE or CITY, FOREIGN STATE, POSTAL CODE

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME *(refer to www.fda.gov/cdrh/prodcode.html)* Internet Link

8. CLASSIFICATION NUMBER Internet Link

9. PROPRIETARY NAME *(Brand Name(s))*

10. COMMON OR USUAL NAME(S)

11. ESTABLISHMENT NAME AND ADDRESS

(Identification of Sites Where Listed Device is Produced)
(Name, Street Number, City, State or Country, ZIP or Postal Code)

REGISTRATION NO.	ESTABLISHMENT TYPE									
	F	M	B	R	S	X				
A										
B										
C										
D										

Public reporting burden for this collection of information is estimated to average 30 minutes 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:

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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.

12. SIGNATURE

13. TYPED OR PRINTED NAME, AND TITLE