DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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

DEVICE LISTING

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	2. REASON FOR SUBMISSION	3. REPORT DATE			4. OWNER / OPERATOR ID NUMBER
		MO.	DAY	YR.	
E	☐ New Listing ☐ Update to Device Already Listed ☐ Delete Listing				

5. OWNER / OPERATOR NAME

6. ADDRESS *(Check ☐ if same as submitted on FDA Form 2891)*

a. NUMBER and STREET

b. CITY, STATE, ZIP CODE

c. FOREIGN COUNTRY

7. CLASSIFICATION NAME ? Internet Link

8. CLASSIFICATION NUMBER ? Internet Link

9. PROPRIETARY NAME *(Brand Name)*

10. COMMON OR USUAL NAME ?

11. **FOR U.S. DESIGNATED AGENTS OF FOREIGN ESTABLISHMENTS**

a. NAME ?

b. REGISTRATION NUMBER ?

12. ? REGISTRATION NO.

ESTABLISHMENT NAME AND ADDRESS

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

? ESTABLISHMENT TYPE

	M	R	S	B	X	F
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.

13. SIGNATURE

14. TYPED OR PRINTED NAME