

**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**

**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  <b>E</b>	2. REASON FOR SUBMISSION  <input type="checkbox"/> New Listing  <input type="checkbox"/> Update to Device Already Listed  <input type="checkbox"/> Delete Listing	3. REPORT DATE			4. OWNER / OPERATOR ID NUMBER
		MO.	DAY	YR.	

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
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7. CLASSIFICATION NAME 	8. CLASSIFICATION NUMBER 
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9. PROPRIETARY NAME (Brand Name)

10. COMMON OR USUAL NAME

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

a. NAME 	b. REGISTRATION NUMBER 
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12.	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
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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:  
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

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
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