

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT
(Shaded Areas are for FDA Use Only)

VALIDATION

RETURN THIS FORM TO: Food and Drug Administration, Center for Devices and Radiological Health, (HFZ-308), 9200 Corporate Blvd., Rockville, MD 20850-4015

1. **REGISTRATION NO.**

Public reporting burden for this collection of information is estimated to average .25 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:

Food and Drug Administration
Center for Devices and Radiological Health (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.

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(q)(2) and may be a violation of 18 U.S.C. 1001.

SECTION A

2. ESTABLISHMENT BUSINESS NAME		3. RECORD DATE (Mo.) (Day) (Year)		
4. NUMBER AND STREET	5. CITY	6. STATE	7. ZIP/POSTAL CODE	
8. FOREIGN STATE	9. FOREIGN COUNTRY		10. PREPRODUCTION REGISTRATION <input type="checkbox"/> YES <input type="checkbox"/> NO	
11. ESTABLISHMENT TYPE (See Instruction Booklet)				
<input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Manufacturer <input type="checkbox"/> Repacker/Relabeler <input type="checkbox"/> Specification Developer <input type="checkbox"/> Reprocessor of Single-Use Device <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Remanufacturer <input type="checkbox"/> Initial Distributor/Importer <input type="checkbox"/> Foreign Exporter				

SECTION B

12. OWNER/OPERATOR BUSINESS NAME		13. OWNER/OPERATOR NUMBER		
14. NUMBER AND STREET	15. CITY	16. STATE	17. ZIP/POSTAL CODE	
18. FOREIGN STATE	19. FOREIGN COUNTRY	20. TELEPHONE NUMBER--IF DIFFERENT FROM THAT OF OFFICIAL CORRESPONDENT (Country, City, Area Code) (Number and Extension)		

SECTION C

21. OFFICIAL CORRESPONDENT (Name of Individual)		22. BUSINESS NAME		
23. NUMBER AND STREET	24. CITY	25. STATE	26. ZIP/POSTAL CODE	
27. FOREIGN STATE	28. FOREIGN COUNTRY	29. E-MAIL ADDRESS		
30. TELEPHONE NUMBER (Country, City, Area Code) (Number and Extension)		31. FAX NUMBER (Country, City, Area Code) (Number)		

SECTION D

32. OTHER BUSINESS TRADING NAMES
(Enter any other name which the establishment in field #2 uses. Do not list Registered trademarks or names of private label distributors. This is usually any name such as a brand name which is not the firm name.)

SEQ	BUSINESS NAME	SEQ	BUSINESS NAME
SO1		SO3	
SO2		SO4	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT	34. TITLE
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