DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

INITIAL REGISTRATION OF DEVICE ESTABLISHMENT

(Shaded Areas are for FDA Use Only)

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

VALIDATION

Print

Clear Form

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): 01 / 01 / 2002

4. NUMBER AND STREET

5. CITY

6. STATE: AL

7. ZIP/POSTAL CODE

8. FOREIGN STATE

9. FOREIGN COUNTRY

10. PREPRODUCTION REGISTRATION ☐ YES ☐ NO

11. ESTABLISHMENT TYPE *(See Instruction Booklet)*

☐ Contract Manufacturer ☐ Manufacturer ☐ Repacker/Relabeler ☐ Specification Developer ☐ Reprocessor of Single-Use Device
☐ Contract Sterilizer ☐ Remanufacturer ☐ Initial Distributor/Importer ☐ Foreign Exporter

SECTION B

12. OWNER/OPERATOR BUSINESS NAME

13. OWNER/OPERATOR NUMBER

14. NUMBER AND STREET

15. CITY

16. STATE: AL

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: AL

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