



Food and Drug Administration
9200 Corporate Blvd, HFZ-308
Rockville, MD 20850-4015

August 20, 2004

MR. JIM KLETT
PHOENIX MEDICAL DEVICES, LLC
1119 ESTELLE LN.,
NEWPORT BEACH, CA 92660
UNITED STATES

Dear Official Correspondent:

This letter provides notification of the registration number assigned to your establishment.

Establishment Name: PHOENIX MEDICAL DEVICES, LLC
Registration Number: 3004620982

If you have any questions or need assistance, please contact CDRH Registration and Listing at (301) 916-9791, Monday through Friday, between 8:00 am and 5:00 pm ET, at reglist@cdrh.fda.gov, or by fax at (301) 916-9798.

Center for Devices and Radiological Health

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.

3004620982

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 Phoenix Medical Devices, LLC		3. RECORD DATE (Mo.) (Day) (Year) 05 16 2004		
4. NUMBER AND STREET 1119 Estelle Lane		5. CITY Newport Beach		6. STATE CA
7. ZIP/POSTAL CODE 92660		8. FOREIGN STATE		9. FOREIGN COUNTRY
10. PREPRODUCTION REGISTRATION <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		11. ESTABLISHMENT TYPE (See Instruction Booklet) <input type="checkbox"/> Contract Manufacturer <input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Repacker/Relabeler <input checked="" 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 Phoenix Medical Devices, LLC		13. OWNER/OPERATOR NUMBER 9064060		
14. NUMBER AND STREET 1119 Estelle Lane		15. CITY Newport Beach		16. STATE CA
17. ZIP/POSTAL CODE 92660		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

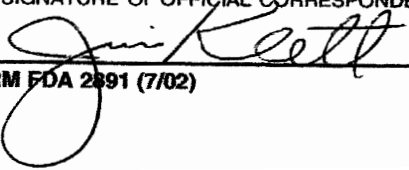
21. OFFICIAL CORRESPONDENT (Name of Individual) Jim Klett		22. BUSINESS NAME Phoenix Medical Devices, LLC		
23. NUMBER AND STREET 1119 Estelle Lane		24. CITY Newport Beach		25. STATE CA
26. ZIP/POSTAL CODE 92660		27. FOREIGN STATE		28. FOREIGN COUNTRY
29. E-MAIL ADDRESS jklett@pmddirect.com				
30. TELEPHONE NUMBER (Country, City, Area Code) (Number and Extension) 949-689-9892			31. FAX NUMBER (Country, City, Area Code) (Number) 949-515-1973	

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
S01		S03	REC'D MAY 20 2004
S02		S04	

SECTION E

33. SIGNATURE OF OFFICIAL CORRESPONDENT 	34. TITLE President
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