JUL 1 1 2006

K061788

2. 510(k) Summary

510(k) Summary

Applicant Information:

Name: Boehringer Laboratories Inc.

Address: 500 E. Washington St.
Norristown PA 19401

Phone: 610-278-0900
Fax: 610-278-0907

Contact: Christopher Radl, Engineering

Trade Name:

Boehringer Laboratories Suction Pump System

Common Name:

Powered Suction Pump

Device Classification:

Class II
Product Code: JCX
Regulation 878.4780
Classification Panel: General & Plastic Surgery

Predicate Devices:

Boehringer Laboratories Suction Pump System	K060277
Versatile 1 Wound Vacuum System	K042134, K052456

Device Description:

The Boehringer Laboratories Suction Pump System consists of a powered suction pump for the application of suction to wounds and for fluid removal. Disposables for use with the pump include: canister, Tube Attachment Device, Cover and Wound Contact Dressing

Intended Use:

The Boehringer Laboratories Suction Pump System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids and infectious materials.

Technological Characteristics:

The modified Boehringer Laboratories Suction Pump System includes the same suction pump and canister as the predicate unmodified device K060277. Additional accessories have been added. These accessories are a Wound Cover, Tube Attachment Device and Wound Contact Dressing. These accessories correspond with accessories available with the predicate Versatile 1 System K042134, K052456. The labeling and indications for use statement have been revised to more specifically cover application of suction to wounds, similar to the predicate Versatile 1 System K042134, K052456.

Conclusion:

The Boehringer Laboratories Suction Pump System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Boehringer Laboratories
% Mr. John R. Boehringer
500 E. Washington Street
Norristown, Pennsylvania 19401

Re: K061788
Trade/Device Name: Boehringer Laboratories Suction Pump System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: June 22, 2006
Received: June 26, 2006

Dear Mr. Boehringer:

This letter corrects our substantially equivalent letter of July 11, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061788

Device Name: **Boehringer Laboratories Suction Pump System**

Indications for Use:

The Boehringer Laboratories Suction Pump System is intended for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudate, irrigation fluids, body fluids and infectious materials.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061788