K060277

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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:

Allied Healthcare Products Gomco Thermotic Drainage Pump	Pre-amendment device
Medela Suction Pumps Median and Vario	K983552

Device Description:

The Boehringer Laboratories Suction Pump System consists of a powered suction pump for the application of low flow suction. A rigid disposable canister for the collection of fluids is included as an accessory.

Intended Use:

The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Technological Characteristics:

The Boehringer Laboratories Suction Pump System is similar to the predicate Gomco Thermotic Drainage Pump and Medela Vario and Median pumps. Areas of similarity include performance parameters, control mechanisms, power source, canister for use with pumps and dimensions.

Conclusion:

The Boehringer Laboratories Suction Pump System is substantially equivalent to the predicate Gomco Thermotic Drainage Pump and Medela Vario and Median suction pumps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2006

Boehringer Laboratories
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K060277
Trade/Device Name: Boehringer Laboratories Suction Pump System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: February 21, 2006
Received: February 23, 2006

Dear Mr. Job:

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 application (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 such 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 begin 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" (21 CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson, M.S.
Acting 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): K060277

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

Indications for Use:

The Boehringer Laboratories Suction Pump System is intended for the application of low flow suction for the removal of fluids, including irrigation fluids, body fluids and infectious materials.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 K060277