K051084

JUN 13 2005

6. 510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on March 17, 2005.

Device Identification

This special 510(k) is for a modification to the Denver Pleurx Drainage Kit.

Intended Use

The Pleurx Drainage Kits are used in conjunction with the Pleurx Pleural Catheter. The devices are intended for long-term, intermittent drainage of symptomatic, recurrent, pleural effusions, including malignant pleural effusions and other pleural effusions that do not respond to treatment of the underlying disease.

Device Description

The Pleurx Drainage Kit includes a vacuum bottle with drainage line that is connected to the Pleurx catheter for removing fluid that has accumulated in the chest. It also includes a procedure pack that includes all the supplies needed to perform the drainage procedure and to replace the dressing over the catheter.

Summary of the change

The special 510(k) addresses changes in the vacuum bottle/drainage line assembly. These changes include

- A larger bottle size has been introduced
- A change in material
- A change in shape
- A change in the sealing/vacuum access mechanism
- A change in the length and diameter of the drainage line
- A change in the sterilization approach, which will maintain sterility of the drainage line but will not sterilize the interior of the vacuum bottle.

This 510(k) also identified minor changes that had been made previously, including a change in the skin antiseptic from povidone-iodine to 70% alcohol.

Substantial Equivalence to Currently Marketed Device

The sponsor used the following techniques to determine that the modified design is substantially equivalent to that of the currently marketed product.

- Verifying that the key safety-critical performance parameter, flow rate, was within the specification for the currently marketed device.
- Verifying that other aspects of the revised bottle design met the specifications set for them.
- Applying risk management techniques to assess the potential impact of the changes on device safety, and adopting appropriate risk control measures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2005

Denver Biomedical, Incorporated
C/O Ms. Nancy Sauer
Director, Regulatory Affairs Quality Assurance
Evergreen Research, Incorporated
433 Park Point Drive, Suite 140
Golden, Colorado 80401

Re: K051084
Trade/Device Name: Pleurx Catheter and Drainage Kits/Vacuum Bottle
Regulation Number: 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM
Dated: May 26, 2005
Received: May 31, 2005

Dear Ms. Sauer:

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.

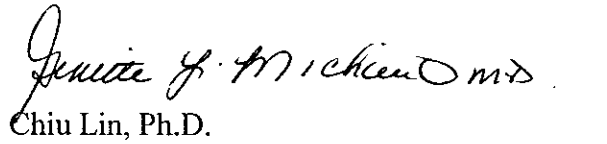
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PLEURX CATHETER AND DRAINAGE KITS/VACUUM BOTTLE

Indications for Use:

The Denver Pleurx Catheter Kit and the Denver Pleurx Drainage Kit/Vacuum Bottle are indicated for intermittent long term drainage of symptomatic, recurrent pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion).

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)

Janette H. Michaud MD

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051084

(Posted November 13, 2003)