OCT 6 - 2005

K052436

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 August 31, 2005.

Device Identification

This special 510(k) is for a modification to the Denver Pleurx Pleural Catheter. The modification is to add an alternate supplier for the velour fabric used to fabricate the cuff. The catheter made with the alternate cuff material has been found substantially equivalent to the previously marketed catheter.

Intended Use

The Pleurx Pleural Catheter is 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 Pleural Catheter is a silicone tube that is partially implanted in the chest cavity. A cuff is included in the tunneled portion of the catheter. The cuff promotes tissue ingrowth, which helps to anchor the catheter and may provide a barrier against infection. The external portion of the catheter includes a valve that remains closed until it is opened with a specific drainage line. When the drainage line is in place, a vacuum source can be used to drain fluid that builds up in the chest cavity.

Summary of the change

The special 510(k) covers a minor material change: a change in the supplier of the fabric used to make the cuff.

The alternate fabric has been found to be equivalent to the previously used fabric by

- Reviewing biocompatibility data to ensure that the fabric is suitable for use in a long-term tissue implant.
- Selecting a fabric with similar physical and chemical specifications
- Testing to ensure that the bond strength between the tubing and the cuff remains within specification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2005

Mr. Jeff Hill
RA/QA Coordinator
Denver Biomedical, Incorporated
14998 West 6th Avenue, Building E700
Golden, Colorado 80401

Re: K052436
Trade/Device Name: Pleurx Pleural Catheter Kit
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM
Dated: September 2, 2005
Received: September 7, 2005

Dear Mr. Hill:

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) 276-0120. 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 Pleural Catheter Kit

Indications for Use:

The Denver® Pleurx Pleural Catheter Kit (#50-7000) and the Denver® Pleurx Drainage Kit (#50-7500) 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)

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

510(k) Number: K052436