

JUN 2 8 2001

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 June 6, 2001.

Device Identification

This special 510(k) is for a modification to the Denver Pleurx Pleural Catheter. The modification is a change in supplier for the tubing used to fabricate the catheter and a change in the velour fabric used to fabricate the cuff. The catheter made of the modified materials has been found substantially equivalent to the legally 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 two material changes: a change in supplier for the tubing used to fabricate the catheter and a change in the fabric used to fabricate the cuff.

The new tubing has been found to be equivalent to the previous tubing by

1. Comparing the dimensional specifications
2. Comparing the physical property specifications
3. Testing to ensure that the bond strength between the tubing and the external valve assembly remains within specification.
4. Testing to ensure that the bond strength between the tubing and the cuff material meets the approved specification.

5. Testing to verify that the tubing meets acceptable standards for biocompatibility for a device in long-term contact with tissue.

The new fabric has been found to be equivalent to the original fabric by a review of material specifications (both are polyester double velour) and by selecting a fabric that has previously been cleared by FDA for use as a cuff material in the chest wall.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2001

Ms. Bonnie Vivian
Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E-700
Golden, CO 80401

Re: K011831
Trade Name: Pleurx pleural catheter and drainage kits
Regulation Number: 870.5050
Regulatory Class: II (two)
Product Code: 74 DWM
Dated: June 11, 2001
Received: June 12, 2001

Dear Ms. Vivian:

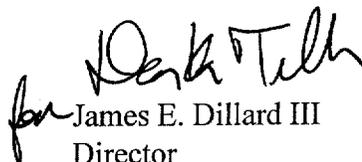
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011831

Device Name: Pleurx Pleural Catheter

Indications For Use:

The Denver® Pleurx® Pleural Catheter Kit and the Denver® Pleurx® Drainage Kit 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).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K011831

(Optional Format 3-10-98)

Prescription Use Only