

NOV 15 2005

## **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 23, 2005 and updated November 10, 2005.

### **Device Identification**

This special 510(k) is for a modification to the intended use of the Pleurx Catheter and Pleurx Drainage Kits.

### **Intended Use**

The Denver Pleurx Peritoneal Catheter Kit and the Denver Pleurx Drainage Kits are indicated for

Intermittent drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease.

Palliation of symptoms related to recurrent malignant ascites.

For peritoneal placement only.

### **Device Description**

The Pleurx Catheter is silicone catheter that can be thought of as containing three zones: the fenestrated zone which is implanted in the body cavity and used to collect fluid; the cuffed zone, which is placed inside a subcutaneous tunnel; and the externalized zone, which includes a valve that remains closed, except when purposefully accessed for a drainage procedure. The Pleurx Drainage Kit includes a vacuum bottle with drainage line that connects to the Pleurx catheter for removing fluid. 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.

### **Substantial Equivalence to Currently Marketed Device**

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

- Verifying that the design and materials are the same or similar to those of legally marketed medical devices, including the existing Pleurx Catheter and other catheters for long-term implantation in the peritoneal cavity.
- Comparing the proposed intended use to the intended use of other legally marketed devices.

- Gathering clinical data to show that the catheter is effective for removing ascites and relieving symptoms until death or ascites resolution in the majority of patients.
- Gathering clinical data to show that for most patients the duration of catheter function is at least twice as long as the interval between paracentesis procedures before catheter placement.
- Gathering clinical data to show that the complication rates associated with the use of the device for malignant ascites are similar to those for other similar devices.
- Applying risk management techniques to assess the potential impact of the change in intended use on device safety, and adopting appropriate risk control measures.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Denver Biomedical, Inc.  
c/o Ms. Nancy Sauer  
Evergreen Research, Inc.  
433 Park Point Drive, Suite 140  
GOLDEN CO 80401

Re: K051711

Trade/Device Name: Pleurx Peritoneal Catheter Kit and Drainage Kits  
Regulation Number: 21 CFR §876.5630  
Regulation Name: Peritoneal dialysis system and accessories  
Regulatory Class: II  
Product Code: FJS  
Dated: November 2, 2005  
Received: November 7, 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 (the Act). You may, therefore, market the device, subject to the general controls provisions of 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 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, 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.

In addition, we have determined that your device kit contains Lidocaine HCl, 1%, and Povidone-iodine swabs which are subject to regulation as drugs.

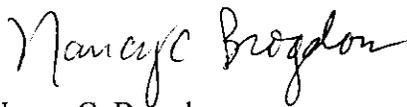
Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 594-0101

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, 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,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K051711

Device Name: Pleurx Peritoneal Catheter Kit and Drainage Kits

Indications for Use:

The Denver® Pleurx Peritoneal Catheter Kit (50-8000) is indicated for:

- Intermittent drainage of symptomatic, recurrent, malignant ascites that does not respond to medical management of the underlying disease
- Palliation of symptoms related to recurrent malignant ascites
- Peritoneal placement only

The Denver® Pleurx Drainage Kits (50-7500 and 50-7510) are indicated for use with either the Pleurx Peritoneal Catheter Kit or the Pleurx Pleural Catheter Kit.

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)

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K051711

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(Posted November 13, 2003)

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