

K971753

**Summary of Safety and Effectiveness  
Denver® PLEURX Pleural Catheter Kit  
Denver® PLEURX Home Drainage Kit**

JUN 27 1997

SUBMITTER INFORMATION

Denver Biomaterials, Inc.  
14998 W. 6th Avenue, Bldg. E700  
Golden, Colorado 80401 USA

Lynne Leonard  
Director, Regulatory Affairs/Quality Assurance

DEVICE COMMON NAME

Patient Care Suction Apparatus

DEVICE CLASSIFICATION NAME

21 CFR 870.5050

IDENTIFICATION OF SUBSTANTIALLY EQUIVALENT DEVICES

The devices are substantially equivalent to the Argyle® Silicone Thoracic Catheter in intended use. They differ in that the Argyle® Silicone Thoracic Catheter is intended for continuous drainage, while the PLEURX Catheter is intended for intermittent, ambulatory drainage.

The devices are substantially equivalent to the Denver® Pleural Effusion Shunt with Externalized Pump Chamber in materials and dimensional specifications. They differ in that the Denver® Pleural Effusion Shunt with Externalized Pump Chamber transfers pleural fluid to the peritoneal cavity, while the PLEURX Catheter transfers fluid to a vacuum source.

Differences between the devices and their predicate devices should not affect their safety or effectiveness.

DEVICE DESCRIPTION:

The Denver® PLEURX Pleural Catheter Kit (#50-7000) is a sterile device, for single use only, and is not to be resterilized. The kit contains the PLEURX Catheter; a specifically matched drainage line that can be configured for either wall suction or a vacuum bottle; and the components needed to place the catheter within the pleural space and to dress the catheter exit site after placement.

The PLEURX Catheter contained in the kit is a flexible, fenestrated silicone catheter with a cuff and a valve. The fenestrated portion of the catheter is inserted into the pleural space utilizing a peel-away introducer (Seldinger technique). The portion of the catheter containing the cuff is tunneled subcutaneously, and the remaining portion is left external to the body. A radiopaque stripe runs the entire length of the catheter.

The Denver® PLEURX Home Drainage Kit (#50-7500), an accessory to the Denver® PLEURX Pleural Catheter Kit, is a sterile, disposable device designed for single use only, and is not to be resterilized. The kit contains drainage lines, vacuum bottles, and the components needed to drain the effusion and to redress the catheter exit site.

#### INDICATED USE

The devices are indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant pleural effusion. They are indicated for the palliation of dyspnea due to malignant pleural effusion, and for providing pleurodesis.

#### BIOCOMPATABILITY TESTING:

The biological safety of the Denver® PLEURX Pleural Catheter Kit has been assured through the selection of materials which are currently used in legally marketed devices.

#### CLINICAL TESTING:

The Denver® PLEURX Pleural Catheter Kit and Denver® PLEURX Home Drainage Kit were evaluated clinically under IDE #930085.

##### 1. Effectiveness of PLEURX Catheter for Relief of Dyspnea

When compared to baseline, subjects showed a significant improvement in their rating of dyspnea after treatment with the PLEURX Catheter, as determined by the Friedman test.

##### 2. Effectiveness of PLEURX Catheter for Improving the Quality of Life

Subjects experienced a significant improvement in quality of life after treatment with the PLEURX Catheter, as determined by the t-test. Although the subjects had serious malignant disease, they experienced an improved ability to carry out daily activities when their pleural effusions were controlled.

##### 3. Effectiveness of PLEURX Catheter for Resulting in Pleurodesis

Approximately half of the subjects treated with the PLEURX Catheter achieved pleurodesis while in the study. No subjects in the PLEURX Catheter arm developed a documented symptomatic recurrence of their effusion.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lynne Leonard  
Director, Regulatory Affairs and Quality Assurance  
Denver Biomaterials, Inc.  
14998 W. 6th Avenue, Bldg. E 700  
Golden, Colorado 80401

JUN 27 1997

Re: K971753  
Denver® PLEURX Pleural Catheter Kit and Denver® PLEURX Home  
Drainage Kit  
Regulatory Class: II (two)  
Product Code: 74 DWM  
Dated: May 8, 1997  
Received: May 12, 1997

Dear Ms. Leonard:

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 (for the indications for use stated in the enclosure) to 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 (Premarket Approval) 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 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 CMP 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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device can not be changed without prior notification, review and clearance by FDA.

In addition, we have determined that your device kit contains lidocaine which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, 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) 594-0063

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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 our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE

510 (K) Number:

K 971753

Device Names:

Denver® PLEURX Pleural Catheter Kit,  
Denver® PLEURX Home Drainage Kit

Indications for Use:

The Denver® PLEURX Pleural Catheter Kit and Denver® PLEURX Home Drainage Kit are indicated for intermittent, long-term drainage of symptomatic, recurrent, malignant pleural effusion. The devices are indicated for the palliation of dyspnea due to malignant pleural effusion and for providing pleurodesis.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Mr. Szymanski M.D.*

*[Signature]* 6/26/17

Prescription Use:  Yes OR Over-the-Counter Use: No  
(Per 21 CFR 801.109)