K973129 P1/2

MAR 17 1998

Summary of Safety and Effectiveness
Denver® Ascites Shunts
Denver® Ascites Shunt Percutaneous Access Kits

SUBMITTER INFORMATION

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

Bonnie Vivian
Vice President

DEVICE COMMON NAME

Peritoneovenous Shunt

DEVICE CLASSIFICATION NAME

Peritoneo-venous Shunt

IDENTIFICATION OF SUBSTANTIALLY EQUIVALENT DEVICE(S)

The devices are substantially equivalent to the currently marketed Denver® Ascites Shunts and Denver® Ascites Shunt Percutaneous Access Kits. The devices have the same intended use, materials, configuration and dimensional specifications as the currently marketed Denver® Ascites Shunts (K894756) and Denver® Ascites Shunt Percutaneous Access Kits (K913728).

The devices differ in that:

1) The devices covered by this submission undergo a surface treatment as part of the manufacturing process.
2) No TDMAC-Heparin is applied to the devices covered by this submission.

The devices are also substantially equivalent to Smith & Nephew Ventilation Tubes in that they both undergo this surface treatment as part of the manufacturing process.

The manufacturing process changes that are the subject of this submission should not raise new issues of safety and/or effectivenenss.

INTENDED USE

Drainage of persistent ascites from the abdominal cavity into the venous system, for use in patients with:

*chronic liver disease whose ascites has not responded to surgical correction of their portal hypertension nor to standard medical management

*persistent ascites who are not considered candidates for portal-venous shunting

*persistent ascites which is non-responsive to standard medical management

*primary or metastatic intra-abdominal neoplasms with massive ascites to help relieve intra-abdominal pressure

*persistent ascites with hepatorenal syndrome, chylous ascites, and idiopathic ascites

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1998

Ms. Bonnie B. Vivian
Vice President
Denver Biomaterials, Inc.
14998 W. 6th Avenue, Bldg. E700
Golden, Colorado 80401

Re: K973129
Denver Ascites Shunts and Percutaneous Access Kits
Dated: December 18, 1997
Received: December 19, 1998
Regulatory Class: III
21 CFR 876.5955/Product Code: 78 KPM

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 (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 (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) 594-4613. 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,

Robert R Saltzman

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K 973129

Device Name: Denver® Ascites Shunts
Denver® Ascites Shunt Percutaneous Access Kits

Indications For Use: Drainage of persistent ascites from the abdominal cavity into the venous system, for use in patients with:

*chronic liver disease whose ascites has not responded to surgical correction of their portal hypertension nor to standard medical management

*persistent ascites who are not considered candidates for portal-venous shunting

*persistent ascites which is non-responsive to standard medical management

*primary or metastatic intra-abdominal neoplasms with massive ascites to help relieve intra-abdominal pressure

*persistent ascites with hepatorenal syndrome, chylous ascites, and idiopathic ascites

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973129

Prescription Use: Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use: No