K052286 1/2

OCT 2 1 2005

Catheter Exchange

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Phone: 323-442-2936
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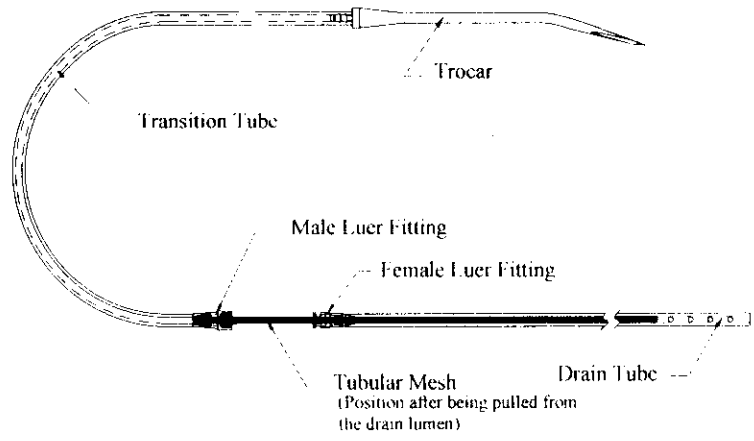
SUMMARY

Submitter's name:	The Catheter Exchange, Inc.
Address:	16633 Ventura Blvd. Suite 735 Encino, CA 91436
Phone: Fax:	323-442-2936 323-442-2913
Name of contact person:	George P. Teitelbaum, M.D. Telephone: 323-442-8948 Fax: 323-442-8969
Date the summary was prepared:	August 12, 2005
Name of the device: Trade or proprietary name: Common or usual name: Classification name:	Deutsch Anti-Blockage Wound Drain Deutsch Anti-Blockage Wound Drain Surgical Wound Drain Catheter, Irrigation
The legally marketed device to which we are claiming equivalence:	Jackson-Pratt Wound Drains. The clearance number K973703 Axiom Multipurpose Wound Drain. The clearance number K993592

DEVICE DESCRIPTION

The wound drain catheter comprises a proximal drain segment, an internal tubular mesh assembled with a luer fitting adapter, a distal transition tube segment, and a metal trocar. The final assembly of the Deutsch Anti-Blockage Wound Drain is illustrated as in the following figure:



1. The drain segment has a uniform cross-sectional area and is made from a silicone elastomer having sufficient elasticity to permit the cross-sectional area of the drain decrease when a pulling force is applied to it, thereby reducing the gripping force of tissue surrounding the wound. The drain segment has distal side holes which are used to drain fluids and exudates during and after surgery.
2. The internal tubular mesh is permanently connected to the inner surface of the luer fitting adapter. In this subassembly, the luer fitting adapter acts as a handle. The tubular mesh is used to re-establish the drain patency when a post-operative occlusion occurs. To do this, the luer fitting adapter needs to be removed from the drain segment end and the luer fitting adapter and the mesh segment to be pulled from the drain lumen to remove the obstructing material. The tubular mesh also provides the catheter radiopacity.
3. The transition tube segment is made from a silicone elastomer with a sufficient elasticity, similar to the drain segment. This transition segment has an internal cavity opening. One end of this transition tube goes over one end of the luer fitting adapter and the other end to the source of suction. When necessary this end is used to insert a metal trocar.
4. The trocar with a sharp distal tip is made from stainless steel. The trocar is used to pull the drain through the surrounding tissue to the intended drainage site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

George P. Teitelbaum, M.D.
CEO/President
The Catheter Exchange, Inc.
16633 Ventura Boulevard, Suite 735
Encino, California 91436

Re: K052286
Trade/Device Name: Deutsch Anti-Blockage Wound Drain
Regulation Number: 21 CFR 878.4200
Regulation Name: Introduction/drainage catheter and accessories
Regulatory Class: I
Product Code: GBX
Dated: August 16, 2005
Received: August 22, 2005

Dear Dr. Teitelbaum:

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) 276-0115. 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,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052286

Indications for Use

510(k) Number (if known):_____

Device Name: Deutsch Anti-Blockage Wound Drain

The anti-clog drain is indicated for use as an adjunctive device during open surgical procedures in order to prevent fluid accumulation within the operative site after closure of the surgical wound.
The device is inserted through the skin adjacent to open surgical incision. The distal end of the drain is positioned within the operative site prior to repair of the incision. The device's proximal end is attached to an appropriate suction source in order to allow efflux of bloody, rosanguinous, chylous, purulent fluid, intestinal, and/or other fluids from the operative site that could impair surgical wound healing. The device is indicated for use in abdominal, thoracic, head and neck, gynecological, urological, spinal, and orthopedic surgical procedures."

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brewer

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052286