MAR 1 0 2003

K030538

510(K) SUMMARY

Device Classification Name: Catheter, Urological
Regulation Number: 876.5130
510(K) Number: Not yet assigned
Device Name: W3 American Catheter
Applicant: Catheter LLC.
P.O. Box 917
106 Groppo Drive
Winsted, CT 06098-0917
Email: john@railroadgage.com
Telephone: (860) 738-7188
Fax: (860) 379-6678
Contact: John C. Devanney
Product Code: KOD

Predicate device:

Device Classification Name: Catheter, Urological
Regulation Number: 876.5130
510(K) Number: K863082
Device Name: COOK-VPI INTERMITTENT CATHETER
Applicant: Cook Urological, Inc.
1100 West Morgan Street
P.O. Box 227
Spencer, IN 47460
Contact: Gerald J. French
Product Code: KOD
Date Received: 08/12/1986
Decision Date: 11/07/1986
Decision: Substantially Equivalent (SE)
Classification Advisory Committee: Gastroenterology
Review Advisory Committee: Gastroenterology
Type: Traditional
Reviewed by Third Party: No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Catheter LLC
c/o Mr. John C. Devanney
106 Groppo Drive
WINSTED, CT 06098 0917

Re: K030538
Trade/Device Name: American Catheter, W3
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EZD
Dated: February 17, 2003
Received: February 20, 2003

Dear Mr. Devanney:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

K030538

510(k) Number ~~Not assigned~~

Device Name: W3 American Catheter with stop shield

Indications for Use:

Used for female intermittent self-catheterization of the bladder. Curved design permits ease of placement. The grip area makes the catheter easier for patients to manipulate.

Non-sterile

Reusable.

Intended for single patient use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030538

(Optional Format 3-10-98)