FEB 2 4 2006

K060268

Non-Confidential Summary of Safety and Effectiveness

30-Jan-06

Clay Kennard
2909 Browne Stone Rd.
Oklahoma City, OK 73120

Tel (405) 840-4224
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Official Contact: Clay Kennard

Proprietary or Trade Name: Urinary catheter

Common/Usual Name: Urinary catheter

Classification Name: Catheter, urethral (and Accessories)

Predicate Devices: ProMedic – K031409

Device Description:

The silicone pediatric urinary catheter is a small diameter tube of various diameters, 3.5, 5.0, 6.5, and 8.0 French and a length of 16". It has an integral female luer fitting. There are 2 eyelets near the tip of the tube. It has marking along the shaft of the tubing and an integral radiopaque line. It is provided sterile.

Intended Use:

Indicated Use --	The urinary catheter is for use with patients requiring urine drainage, with chronic urine retention and with post void residual volume (PVR). The catheter is inserted into the urethra to reach the bladder allowing urine to drain.
Environment of Use --	Hospital, sub-acute, and environments where placement of a urinary catheter is required.

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Comparison to Predicate Devices:

Attribute	**Proposed device**	**Predicate ProMedic K031409**
Intended use		
To be placed into the urethra to permit urine drainage.	Yes	Yes
Intended for single patient use < 30 days	Yes	Yes
Prescription	Yes	Yes
Intended population infants	Yes	Yes
Intended Environment of Use - Hospital, sub-acute or environments where placement of urinary catheters is required.	Yes	Yes
Design Features		
Provided in various diameters from 3.5 to 8 Fr	3.5, 5, 6.5, 8 Fr	3.5, 5, 6.5, 8 Fr - Yes
Standard female luer connector	Yes	Yes
Two (2) eyelet holes near tip	Yes	Yes
Radiopaque line entire length of tubing	Yes	Yes
Markings along the length of the tubing	Yes	Yes
Materials		
Tubing – Silicone and Connector - PP	Yes	Yes
Packaging		
Sterile	Yes	Yes
Performance		
None under Section 514	Yes	Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicate – ProMedic, Inc. Urinary Catheter – K031409.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2006

Mr. Clay Kennard
2909 Browne Stone Road
OKLAHOMA CITY OK 73120

Re: K060268
Trade/Device Name: Pediatric Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: GBM
Dated: January 30, 2006
Received: February 1, 2006

Dear Mr. Kennard:

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

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

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

Enclosure

510(k) Number: K060268 (To be assigned)

Device Name: Pediatric Urinary Catheter

Indications for Use: The urinary catheter is for use with patients requiring urine drainage, with chronic urine retention and with post-void residual volume (PVR). The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060268