OCT 1 1 2005

Mentor Self-Cath® HydroGel™ Intermittent Urethral Urinary Catheter

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K052440

Contact Person: Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Telephone: 805-879-6304
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Date Prepared: December 30, 2004

Device Name and Classification

Trade Name: Mentor Self-Cath® Hydrogel™ Intermittent Urethral Urinary Catheter

Common Name: Urinary Catheter

Classification Name: Urological Catheter and Accessories

Product Code: 78 EZL

Manufacturer

Mentor Minnesota
1601 West River Road North
Minneapolis, MN 55411

Device Description

The Mentor Self-Cath® HydroGel™ catheter (hereafter referred to as SCHG) is an extension of the existing Mentor Self-Cath product line. The device is a modification of the Mentor Self-Cath® Plus catheter and the Mentor Self-Cath Closed System catheter.

The SCHG is intended to be used to drain urine from the bladder. It is provided sterile and is for single-use only. It consists of a prelubricated catheter with an introducer tip on the proximal end which is designed to reduce patient contact and

potential contamination while advancing the catheter into the urethra. The catheter is prelubricated with a water-soluble hydrophilic water-based lubricant. The catheter is packaged inside a thin flexible telescoping sleeve that is designed to extend from the catheter to the urine collection device or toilet during bladder voiding. The distal end of the sleeve includes a drainage port with a suction cup for attachment to the toilet, thus stabilizing the sleeve during the voiding process. The SCHG also has a reduced package size for ease of transport.

The SCHG is available singly or as a kit with the following accessories included: non-latex gloves, a paper poly towel, PVP swabs, and a BZK towelette.

Substantial Equivalence Claim

Mentor Corporation believes the proposed Mentor SCHG is substantially equivalent in form and function to Mentor's Self-Cath Plus Catheter and the Self-Cath Closed System, which were cleared under 510(k)s K003874 and K003873, respectively.

Indications for Use

The Mentor Self-Cath® HydroGel™ Intermittent Urethral Urinary Catheter is intended for use in male, female and pediatric patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode

Summary of Testing

Mentor has performed biocompatibility testing on the SCHG:

Cytotoxicity (Agar Diffusion – ISO Method): The catheter portion of the test article did not induce cytotoxicity. The introducer tip portion did introduce cytotoxicity; however, the reactivity was less that a Grade 2 (mild reactivity). Therefore, the test article does meet the criteria of this test.

Guinea Pig Maximization (Saline and Vegetable Oil Extracts): There were no signs of sensitization observed in guinea pigs treated with the test article. Therefore, the test article is not considered to elicit contact dermal allergenicity.

Systemic Toxicity (Acute Systemic Injection with Saline and Vegetable Oil Extracts: The test article met the requirements of the systemic injection test.

Acute Vaginal Irritation: The test article meets the requirements of the vaginal irritation test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2005

Ms. Donna A. Crawford
Director, Domestic Regulatory Submissions
Mentor Corporation
201 Mentor Drive
SANTA BARBARA CA 93111

Re: K052440
Trade/Device Name: Mentor Self-Cath® HydroGel™ Intermittent Urethral Urinary Catheter
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: September 23, 2005
Received: September 26, 2005

Dear Ms. Crawford:

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

Indications for Use

510(k) Number (if known): K052440

Device Name: Mentor Self-Cath® HydroGel™ Intermittent Urethral Urinary Catheter

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052440