MAY 1 4 2013

5.0 510(k) Summary

510(k) Submitter:

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Contact Name:

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Date prepared: August 28, 2012

Trade or Proprietary Name: HydroSil, Magic, Personal Catheter

Common or Usual Name: Urological Catheter

Classification Name: Urological catheter and accessories
(21 CFR 876.5130, Product Code EZD)

Predicate Device(s):

K000723 Rochester Medical Corporation
Personal® Catheter (Hydrophilic)

K072808 Coloplast Corp.
SpeediCath Compact

Device Description:

The Hydrophilic Intermittent Urinary Catheter is made from silicone elastomer with a hydrophilic coating. The device is for urological use only. It is intended for use by patients for bladder management including urine drainage, collection, and measurement.

The device consists of an all silicone elastomer single lumen catheter and includes a silicone handle. The catheter has drainage eyes located in the proximal tip and a tapered funnel located at the distal end. The outer surface of the all silicone catheter has a hydrophilic coating which binds water molecules to the surface creating a smooth lubricating film. The handle provides the patient-user an ergonomically designed area for a secure grip and no-touch area when inserting the catheter.

Intended Use of the Device:

For urological use only. Intended for use by patients for bladder management including urine drainage, collection and measurement. The devices are passed to the urinary bladder via the urethra.

Technological Characteristics:

The device described in the 510(k) is an all silicone single lumen drainage tube with drainage eyes at the proximal end and a tapered funnel at the distal end. The predicate devices are also made from similar materials such as silicone and polyurethane. The 510(k) device has an outer hydrophilic coating which is hydrated with sterile water. The predicate devices also have an outer hydrophilic coating, which is hydrated in the similar manner such as sterile water and saline solution. The 510(k) device has a handle designed to facilitate ease of catheter insertion. The predicate devices may also have a handle. All of the devices are supplied sterile for single use.

Non-Clinical Performance Data

The following non-clinical performance data demonstrates substantial equivalence of the 510(k) device to the predicate devices:

Design Qualification

- Hydrophilic Intermittent Catheter with a Handle - VAL439, TR1691. This non-clinical test data includes: dimensional analysis, appearance, and functional testing according to EN 1616. Lubricity testing was conducted according to modified ASTM D1894.

Long Term Stability/Shelf Life

- Hydrophilic Intermittent Catheter with a Handle – LTS096. This non-clinical test data includes: dimensional analysis, appearance, and functional testing according to EN 1616.

Biocompatibility

- ISO 10993-5, Cytotoxicity
- ISO 10993-10, Sensitization GPMT (Klingman), 2 extracts
- ISO 10993-10, Vaginal Irritation w/Histopathology, 2 extracts

Conclusion:

Substantial equivalence of the Hydrophilic Intermittent Urinary Catheter is supported by a comparison of the design and intended use compared to the predicate devices which received marketing clearance under Premarket Notification, as well as acceptable results from functional performance and biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2013

Rochester Medical Corporation
% Mr. Robert Anglin
Vice President of Quality and Regulatory
One Rochester Medical Drive
STEWARTVILLE MN 55976

Re: K122785
Trade/Device Name: Hydrophilic Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: April 11, 2013
Received: April 19, 2013

Dear Mr. Anglin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122785

DEVICE NAME: Hydrophilic Intermittent Urinary Catheter

INDICATIONS FOR USE:

For urological use only. Intended for use by patients for bladder management including urine drainage, collection and measurement. The devices are passed to the urinary bladder via the urethra.

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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122785