K072539
Page 1 of 2

SEP 13 2007

510(k) SUMMARY

Submitted by:

Ann Kenowsky
Cure Medical, LLC
2113 Seville Avenue
Newport Beach, CA 92661
805-928-0109 (Phone)
949 723-4818 (Fax)
E-mail: akyant@aol.com

Contact Person:

James Smith, Ph.D., RAC
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510
Laguna Niguel, CA 92677
949-340-7261 (phone)
949-340-7141 (fax)
E-mail: jrsmith@bentleybiomed.com

Date Prepared: August 11, 2007

Device Name: Cure Catheter™

Trade Name: Cure Catheter™

Common Name: Intermittent Urinary Catheter

Classification Name: Catheter, Urological

Device Class: II

Procode: KOD

CFR Reference: 876.5130

Predicate Device: Rusch Easy Cath Intermittent Catheters

Predicate 510(k) #: K033023 (Rusch)

Device Description: The Cure Catheter™ device is an intermittent urinary catheter intended to be used by males and females for the purpose of bladder drainage. It is manufactured with conventional medical grade, latex-free, biocompatible materials. The tip has been designed to eliminate trauma to the urethra and is provided in a variety of sizes in easy-to-open, sterile, single-use packages.

Intended Use: The Cure Catheter™ is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females.

K072539
Page 2 of 2

Technology Comparison: The Cure Catheter™ is substantially equivalent to the predicate device. The two devices are similar in function, composition, and intended use.

Nonclinical Testing: Standard biocompatibility tests were performed on the Cure Catheter™ to establish device safety. The tests and assays performed are typically performed for these medical devices. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North America Science Associates, Inc. (NAmSA). The studies indicated that the Cure Catheter™ is biocompatible and safe for its intended use.

Conclusion of Comparison: The Cure Catheter™ is substantially equivalent to the currently-marketed predicate device, the Rusch Easy Cath Intermediate Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 13 2007

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Cure Medical, LLC
c/o Mr. Casey Conry
Senior Project Engineer
Underwriters Laboratories, Inc.
1285 Walt Whitman Road
MELVILLE NY 11747

Re: K072539
Trade/Device Name: Cure Catheter™
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD and GBM
Dated: September 7, 2007
Received: September 10, 2007

Dear Mr. Conry:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
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): ~~N/A~~ K072539

Device Name: Cure Catheter™

Indications for Use:

The Cure Catheter™ is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072539

CURE MEDICAL • 2113 Seville Ave. • Newport Beach, CA 92661 • 800 570-1778 • www.curemedical.com