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5. 510(k) Summary

SUMMARY

AUG - 1 2011

Submitter's name: Cure Medical, LLC

Address: 2113 Seville Avenue
Newport Beach, CA 92661

Phone: 949-673-5117
Fax number: 949 723-4818

Name of contact person: Robyn Scopis
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606
Phone: 949-262-0411
Fax: 949-552-2821

Date the summary was prepared: July 28, 2011

Name of the device: Cure Pediatric Catheter
Trade or proprietary name: Cure Pediatric Catheter
Common or usual name: Intermittent Urinary Catheter
Classification name: Catheter, Straight
Classification 2
Product Code EZD

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K072539	1	Cure Catheter	1	Cure Medical
2	K080881	2	Cure Catheter Closed System	2	Cure Medical

Description of the device:

The Cure Pediatric Catheter device is an intermittent urinary catheter intended to be used by pediatric 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.

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Indications:
An intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for pediatric males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

Summary of the technological characteristics of our device compared to the predicate device:

The Cure Pediatric Catheter is substantially equivalent to the predicate devices. The catheter design is identical to both predicates K072539 and K080881 (except in length) and materials are identical to the predicate K080881.

Summary of Nonclinical Testing:

Standard biocompatibility tests were performed on the Cure Catheter to establish device safety. All tests were performed in accordance with ISO10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The studies indicated that the Cure Pediatric Catheter is biocompatible and safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Cure Medical, LLC
% Ms. Robyn Scopis
Regulatory Specialist
Regulatory Specialist, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

AUG - 1 2011

Re: K110653
Trade/Device Name: Cure Pediatric Catheter by Cure Medical, LLC
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: July 25, 2011
Received: July26, 2011

Dear Ms. Scopis:

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, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K110653

Device Name: Cure Pediatric Catheter by Cure Medical, LLC

Indications for Use:
An intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for pediatric males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K110653

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