DEC 2 3 2013

510(k) SUMMARY

Submitted by:	Ann Kenowsky, President Cure Medical, LLC 3700 Newport Blvd., #301 Newport Beach, CA 92663 949 673 8474 (Phone) 949 723 0564 (Fax) email: akenowsky@curemedical.com
Contact person:	John Beasley, MS, RAC (US) MedTech Review, LLC 257 Garnet Garden Street Henderson, NV 89015 612 889 5168 (Phone) email: john@medtechreview.com
Date Prepared:	10 November 2013
Trade Name:	Cure Catheter ™ Hydrophilic Coated
Common Name:	Urinary catheter for intermittent use
Classification Name:	Urological catheter
Device Class:	II
Procode:	EZD (catheter, straight)
CFR Reference:	876.5130
Predicate Device(s):	Cure Medical Cure Catheter | K072539 Cure Pediatric Catheter | K110653
Reference Devices(s):	Astra Tech AB LoFric® Primo™ Single Use Urinary Catheter | K050874 Coloplast SpeediCath | K023254
Device Description:	The Cure Catheter ™ Hydrophilic Coated is an intermittent urinary catheter intended to be used by adult and pediatric males and females for the purpose of bladder drainage. The catheter is manufactured with conventional medical grade PVC. The surface is coated with a hydrophilic low-friction coating (polyvinyl pyrrolidone, or PVP) and, when activated

with water it becomes slippery and ready to use. The straight and Coudè tip configurations have been designed to eliminate trauma to the urethra and are offered in a variety of sizes. Each catheter is provided in sterile, single-use packages.

Intended Use:

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

Technology Comparison:

The Cure Catheter ™ Hydrophilic Coated and listed predicate devices are all similar in device function, features, composition, and intended use as listed in the following table:

Characteristics	Proposed Device	Predicate Devices		Reference Devices	
	Cure Catheter ™ Hydrophilic Coated	**Cure Medical Cure Catheter™**	**Cure Medical Cure Pediatric Catheter™**	**Astra Tech AB LoFric® Primo™ Single Use Urinary Catheter**	**Coloplast SpeediCath**
510(k)	/	K072539	K110653	K050874	K023254
Device Features	Hydrophilic coated, with water sachet. Low friction between catheter and urethral mucosa. Ready to use.	No coating	No coating	Hydrophilic coated, with water integrated in the package. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.
Sizes[1]	Female 6 inch Straight Tip Ch 6, 8, 10, 12, 14, 16, 18 Male 16 inch Straight and Coudè Tip Ch 8, 10, 12, 14, 16, 18 Pediatric 10 inch Straight Tip Ch 6, 8, 10, 12, 14	Female Straight Tip 6 inch Ch 8, 10, 12, 14, 16, 18 Male Straight Tip 16 inch Ch 8, 10, 12, 14, 16, 18	Pediatric, 10 inch Straight Tip, Ch 8, 10, 12, 14	Female 150mm Ch 8, 10, 12, 14 Female 200mm Ch 8, 10, 12, 14, 16, 18 Male Ch 8, 10, 12, 14, 16, 18, 20, 22, 24 Tiemann Ch 10, 12, 14, 16, 18 Pediatric 200mm Ch 6, 8, 10 Boy Ch 6, 8, 10	Female Ch 6, 8, 10, 12, 14, 16 Male Ch 8, 10, 12, 14, 16, 18 Tiemann Ch 10, 12, 14 Pediatric Ch 6, 8, 10 Boy Ch 6, 8, 10, 12

[1] The name and the symbol "Ch" refer to the Charrière gauge scale, which is often called the French scale.

Cure Medical - **Cure Catheter® Hydrophilic Coated** Special 510(k) Submission

Characteristics	Proposed Device	Predicate Devices		Reference Devices	
	Cure Catheter ™ Hydrophilic Coated	**Cure Medical Cure Catheter™**	**Cure Medical Cure Pediatric Catheter™**	**Astra Tech AB LoFric® Primo™ Single Use Urinary Catheter**	**Coloplast SpeediCath**
510(k)	/	K072539	K110653	K050874	K023254
Sterility	STERILE	STERILE	STERILE	STERILE	STERILE
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack	Peel Pack
Device composition	Polyvinyl Chloride (PVC) Catheter with DSM Comfort Coat – polyvinylpyrrolidone - Hydrophilic Material Coating - and sterile water sachet	Polyvinyl Chlorine Catheter without hydrophilic coating	Polyvinyl Chlorine Catheter without hydrophilic coating	Polyvinylchloride catheter coated with polyvinylpyrrolidone and salt. Packaged with water sachet.	Polyurethane catheter coated with polyvinylpyrrolidone, placed in a saline solution containing polyvinylpyrrolidone.
Intended Use	Intermittent catheterization, through the urethra, for the purpose of bladder drainage for males and females.	Intermittent catheterization, through the urethra, for the purpose of bladder drainage for males and females..	Intermittent catheterization through the urethra for the purpose of bladder drainage for pediatric males and females.	Intermittent catheterization of the urethra.	Chronic urine retention. Post-void residual volume (PVR). Voiding dysfunctions.

Performance Testing:

Studies conducted per US FDA General Program memorandum #G95-1 indicate that the Cure Catheter ™ Hydrophilic Coated is biocompatible and safe for its intended use.

Moreover, product evaluation, through design verification and design validation activities, supports the device's functionality without new questions of safety or effectiveness.

Conclusion of Comparison: The Cure Catheter ™ Hydrophilic Coated is substantially equivalent to the currently marketed predicate devices.

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

December 23, 2013

Cure Medical, LLC
c/o John Beasley, MS, RAC
Founder and Senior consultant
Medtech Review, LLC
257 Garnet Garden Street
Henderson, NV 89015

Re: K132500
Trade/Device Name: Cure Catheter® Hydrophilic Coated
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD
Dated: November 25, 2013
Received: November 26, 2013

Dear Mr. John Beasley:

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 contact 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. 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

Indications for Use

510(k) Number (if known): K132500

Device Name: **Cure Catheter ® Hydrophilic Coated**

Indications for Use:

The Cure Catheter ® Hydrophilic Coated is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage. 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
2013.12.23 09:57:47 -05'00'