



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 26, 2016

CompactCath Inc.
Naama Stauber Breckler
CEO
887 Federation Way
Palo Alto, CA 94303

Re: K160858
Trade/Device Name: CompactCath Intermittent Urinary Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: EZD
Dated: March 25, 2016
Received: March 29, 2016

Dear Naama Stauber Breckler,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,


Benjamin R. Fisher -S

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)

K160858

Device Name

CompactCath Intermittent Urinary Catheter

Indications for Use (Describe)

CompactCath is indicated for use in male, female, and pediatric patients (adolescents and transitional adolescents) with chronic urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CompactCath, Inc.
Special 510(k)

25 March 2016
CompactCath Intermittent Urinary Catheter

510 (k) Summary

Company Information

<u>Submitter</u>	CompactCath Inc. 887 Federation Way Palo Alto, CA, 94303 Tel: 408-893-9776
<u>Contact</u>	Naama Stauber Breckler CEO

Device Information

<u>Trade Name</u>	CompactCath Intermittent Urinary Catheter
<u>Common Name</u>	CompactCath Intermittent Urinary Catheter
<u>Classification</u>	Class II
<u>Regulation</u>	21 CFR 876.5130
<u>Product Code</u>	EZD

Indications for Use

CompactCath is indicated for use in male, female, and pediatric patients (adolescents and transitional adolescents) with chronic urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

Predicate Devices

K140945	CompactCath Intermittent Urinary Catheter
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Device Description

The CompactCath Intermittent Urinary Catheter is a sterile, single use urine drainage catheter for use in draining urine from the bladder in subjects with urine drainage problems.

Comparison with the predicate device

The CompactCath Intermittent Urinary Catheter is equivalent to the features of the predicate product. The indications for use, theory of operation, clinical application, methods of manufacturing, and materials used are substantially equivalent. Both devices are intended for insertion into the urethra, advancing to the bladder and to provide a

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pathway for the drainage of urine in male, female and pediatric patients. Both devices are packaged in a Tyvek pouch, heat-sealed and sterilized. Both devices are intended for single use only.

Performance Testing

Product testing was completed and met the acceptance criteria. Testing included flow measurements, bond strength, deployment, and insertion force using anatomical models to simulate clinical use for both the CompactCath device and the predicate device. Test results show the products are equivalent.

Biocompatibility testing was performed per ISO10993 for the original application. Cytotoxicity was conducted for the special 510(k). All materials were found to be biocompatible and suitable for this use.

Sterilization validation and expiry dating were also completed.

Sterilization

The system is provided sterile and is for single use only.

Packaging

The components are placed in a heat sealed Tyvek pouch.

Materials

All materials used in the manufacture of the CompactCath Intermittent Urinary Catheter are suitable for this use and have been used in previously cleared products. The direct patient contacting material is the same as the predicate device. Both devices use silicone as a lubricant for ease of insertion.

Conclusion

The modified CompactCath Intermittent Urinary Catheter is as safe and effective, has the same intended use, technological characteristics and principals of operation as the unmodified predicate device. The minor differences between the modified and the predicate device do not raise any new questions of safety or effectiveness. Therefore, the modified CompactCath Intermittent Urinary Catheter is substantially equivalent.