



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

August 21, 2014

CompactCath
% Gregory Mathison
President
Regulatory Strategies, Inc.
3924 Cascade Beach Road
Lutsen, MN 55612

Re: K140945
Trade/Device Name: CompactCath Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: June 30, 2014
Received: August 14, 2014

Dear Gregory Mathison,

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

Indications For Use

Indication

CompactCath Intermittent Urinary Catheter is indicated for use in male, female, and pediatric patients (*adolescent and transitional adolescent*) 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.

Indications of Use Red-line version:

Indication

CompactCath Intermittent Urinary Catheter is indicated for use in male, female, and pediatric patients (*adolescent and transitional adolescent*) 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.

Indications for Use

510(k) Number (if known)

K140945

Device Name

CompactCath Intermittent Urinary Catheter

Indications for Use (Describe)

CompactCath Intermittent Urinary Catheter is indicated for use in male, female, and pediatric patients (adolescent and transitional adolescent) 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 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Modified 510(K) Summary

510(k) Summary

Date of Submission: March 31, 2014

Classification Class II

Trade Name CompactCath Intermittent Urinary Catheter

Submitter CompactCath Inc.
2945A Bush St
San Francisco, CA, 94115

Contact:
Gregory Mathison
Regulatory Affairs

Indications for Use

The CompactCath Intermittent Urinary Catheter is indicated for use in male, female, and pediatric patients (adolescent and transitional adolescent) 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

K100878 Self Cath Catheter Coloplast A/S

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.

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.

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. All materials were found to be biocompatible and suitable for this use.

Sterilization validation and expiry dating were also completed.

Summary of Substantial Equivalence

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 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.

Refer to the table below for comparison data and substantial equivalence rationale

Feature/ Information	CompactCath	Coloplast	Substantial Equivalence
Manufacturer	CompactCath Inc.	Coloplast A/S	
510(k) Number	K140945	K100878	
FDA Classification	Class II	Class II	Same
Regulation number	876.5130	876.5130	Same
Product Code	EZD	EZD	Same
Indications for Use	The CompactCath Intermittent Urinary Catheter 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.	The Self Cath Catheter is intended for use in male, female, and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.	Equivalent – both devices are indicated for bladder drainage in males, females and adolescents, and transitional adolescents patients. Intermittent catheterization is indicated for patients who have residual urine remaining in their bladder.
Technology & Design / Description	Tubular catheter which is inserted into the urethra and advanced into the bladder to facilitate urine drainage	Tubular catheter which is inserted into the urethra and advanced into the bladder to facilitate urine drainage	Equivalent – both devices are tubular catheters that allow urine drainage when inserted into the urethra to the bladder
Materials	Catheter - PVC	Catheter - PVC	Equivalent – same base materials – exact vendor and classification of predicate

				material unknown.
Physical Dimensions	Length	16" (for adults), 10" (for pediatric)	16" (for adults) , 10" (for pediatric)	Same
	Diameter	8-12FR	8-18FR	Same
	Number of eyelets	2	2	Same
Clinical Procedure	Inserted into the urethra and advanced into the bladder to facilitate urine drainage	Inserted into the urethra and advanced into the bladder to facilitate urine drainage	Equivalent – same clinical application – device is introduced into the urethra and advanced to the bladder to facilitate urine drainage	
Theory of Operation	Provides a pathway for urine drainage	Provides a pathway for urine drainage	Same	
Lubricated	Yes - silicone	Yes - silicone	Equivalent – both catheters are pre-lubricated for ease of use and patient comfort	
Method of Sterilization	Radiation	ETO	Equivalent – both devices are provided sterile. CompactCath is sterilized with Radiation in a validated cycle. Predicate device is sterilized using ETO gas.	
SAL	10 ⁻⁶	Unknown	Equivalent - assumed to be 10 ⁻⁶ as this is a FDA cleared product	
Single Use	Yes	Yes	Same	
Shelf Life	6 months	2 Years	Equivalent	
Packaging	Tyvek pouch	Tyvek pouch	Equivalent	
Performance specifications & testing summary (avg.)	Insertion force	Female 0.08 lbf Male 1.08 lbf	Female 0.06 lbf Male 1.38 lbf	
	Flow test	504 ml/min	520 ml/min	
	Hub pull	17.97 (lbf, {N})	14.96 (lbf, {N})	