DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 1, 2014

ConvaTec Ltd.
Clare Williamson
Senior Regulatory Affairs Executive
Unit 20, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
UK

Re: K140953
Trade/Device Name: GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: June 24, 2014
Received: June 27, 2014

Dear Clare Williamson,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140953

Device Name

GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter

Indications for Use *(Describe)*

Intermittent catheters are single use devices indicated for routine short term drainage of the bladder. The catheter is inserted through the urethra.

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)

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)*

Herbert P. Lerner -S
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Section 5

510(k) Summary

Applicant: ConvaTec Ltd.

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Contact: Clare Williamson
Senior Regulatory Affairs Executive

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Date Prepared: April 07, 2014

Device Identification:

Trade Name: GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter

Common Name: Urological Catheter

Regulation Number: 21 CFR §876.5130

Classification Panel: Gastroenterology and Urology

Classification Name: Urological catheter and accessories

Regulatory Class: II

Product Code: KOD

Product Reference: 508979, 508980, 508981, 508982, 508983, 508984

Predicate Devices:

510(k) number: K896729	GentleCath Male Tiemann Intermittent Urinary Catheter (formerly known as Unoplast Nelaton-, Female- or Tiemann Catheter) Product reference: 501011, 501012, 501013, 501014, 501015, 501016
510(k) number: K100878	Self-Cath Olive Tip Coudé Male Intermittent Urinary Catheter Product reference: 504710/808, 504720/810, 504730/812, 504740/814, 504750/816, 504760/818

Device Description

The intermittent urinary catheter is a thin hollow tube, fitted with a connector at one end and an olive tip (ball) at the other, which is inserted intermittently through the urethra and up to the bladder so that urine can drain. Both components are prepared from plastic materials and are bonded by cyclohexanone. The products are designed for transient use only and are available in various diameters; six FR (CH) sizes: FR08, FR10, FR12, FR14, FR16 and FR18. An increasing French size corresponds to a larger external diameter.

The catheter is primary packaged in a paper/film peelpack and is sterilized by Ethylene Oxide.

The catheter tube has a smooth, clear surface with two lateral eyelets and closed angled tip with small ball called an olive. Eyelets are placed on the left and right site of the catheter and the angled portion of the catheter tip is oriented upward.

Intended Use

The GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter is a single use device indicated for the routine short term drainage of the bladder. The catheter is inserted through the urethra.

Performance Testing - Bench

Details relating to performance testing of the subject device and the 2 predicate devices can be found in section 18 of this submission. The following comparison tests were performed to demonstrate substantial equivalence:

1) Catheter Flow Rate
2) Strength of Tube and Connector Attachment
3) Angle of Coudé Tip
4) Diameter of Ball

The laboratory testing shows no differences that would indicate the GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter would be any less safe or effective than the predicate devices. All the parameters are similar or superior for

the GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter. Therefore, the testing has demonstrated substantial equivalence of the GentleCath Male Coudé Olive Tip Intermittent Urinary Catheter to the predicate devices.

Substantial Equivalence Conclusion

It has been demonstrated through comparison of design and features and performance testing, that the proposed device and its predicates have been found to be substantially equivalent; see following pages.