November 21, 2017

ConvaTec Limited
Hannah Sharp
Regulatory Affairs Specialist
First Avenue, Deepside Industrial Park
Deeside, Flintshire CH5 2NU
United Kingdom

Re: K172924
Trade/Device Name: GentleCath™ Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: September 26, 2017
Received: September 28, 2017

Dear Hannah Sharp:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172924

Device Name

GentleCath™ Intermittent Urinary Catheter

Indications for Use *(Describe)*

Intermittent Catheters are 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5
510(k) Summary

Applicant: ConvaTec Limited.

Applicant Address: ConvaTec Limited (GDC),
First Avenue,
Deeside Industrial Park,
Deeside,
Flintshire,
CH5 2NU,
UK

The Establishment Registration number is 1000317571

Contact: Hannah Sharp
Regulatory Affairs Specialist

ConvaTec Limited (GDC)
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Flintshire, CH5 2NU
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Tel: +44(0) 1244584145

Date Prepared: 20th October 2017

Device Identification:

Trade Name: GentleCath™ Intermittent Urinary Catheter.

Common Name: Catheter, urethral

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: 419800, 501002, 501003, 501004, 501005, 501006, 501011, 501006, 501011, 501012, 501013, 501014, 501015, 501016, 501019, 501020, 501021, 501022, 501023

Predicate Devices:

Primary Predicate:
510(K) number: K140953-GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter

Secondary Predicate:
510(k) number: K100878-Self-Cath® Intermittent Urinary Catheter

Device Description

The GentleCath™ Intermittent Urinary Catheter is labelled as a single use, sterile device and is sterilized by Ethylene Oxide to a Sterility Assurance Level of $10^{-6.}$ A urological catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids from the bladder. tip/distal end of the tube is inserted into the urethra and the funnel/connector end is used to drain the urine or can be connected to a urine drainage bag. Both components of the device are made using Polyvinyl chloride (PVC) as base material and bonded with Cyclohexanone. The products are designed for transient use only and are available in various diameters; Six FR/CH sizes: CH08, CH10, CH12, CH14, CH16, CH18. An increasing Charrière corresponds to a larger external diameter.

Indication for Use

GentleCath™ Intermittent Urinary Catheter are indicated for routine short term drainage of the bladder. The catheter is inserted through the urethra.

The Indications for Use statement for the GentleCath™ Intermittent Urinary Catheter is identical to the primary predicate, GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter but differs from the Secondary Predicate, Self-Cath® Intermittent Urinary Catheter. Self-Cath® Intermittent Urinary Catheters do not state a usage duration, however, the differences do not alter the intended therapeutic use of the devices nor do they affect the safety and effectiveness of the devices relative to the predicate. Both the subject and predicate devices have the same intended use for bladder drainage.

Intended Use Population

GentleCath™ Intermittent Urinary Catheter is intended for male, female and paediatric patients (children, adolescents and transitional adolescents).

Comparison of the Technological Characteristics with the Predicate Devices.

Intermittent bladder drainage is the technological principle for both the subject and predicate devices. It is based on the use of an intermittent catheter facilitating bladder drainage when required by the end user. The subject device and predicate devices are based on the following same technological elements:

- All products inserted through urethra
- Singe use products
- Intended for intermittent catheterization
- Device configuration is the same, consisting of a tube and connector with funnel
- Use of Ethylene Oxide as sterilization method
- Same colour coding of connectors
- All devices are uncoated catheters

The following technological differences exist between the subject and predicate devices.

- Use of different plasticizer (DEHP) within secondary predicate device

Performance Testing – Bench

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

1)Flow Rate

2)Catheter Tensile properties

3)K Dimension

The laboratory testing shows the GentleCath™ Intermittent Urinary Catheter performs similarly to the predicate devices. All the results are similar or superior for the GentleCath™ Intermittent Urinary Catheter. Therefore, the testing has demonstrated substantial equivalence of the GentleCath™ intermittent Urinary Catheter to predicate devices.

Substantial Equivalence Conclusion

It has been demonstrated through comparison of design features and performance testing, that the proposed device and its predicates are substantially equivalent; see following pages. The bench testing performed on the subject device and the predicate devices supports the safety of the devices, this demonstrates that the GentleCath™ Intermittent Urinary Catheter should perform as intended. This data demonstrates that the subject device performs comparably to the predicate devices that are currently marketed for the same intended use.

ConvaTec

Substantial Equivalence Discussion

ConvaTec Limited has been manufacturing intermittent urinary catheters for several decades, dating back to the clearance of K896729- Nelaton, Female or Tiemann Catheter determined substantially equivalent on 5th November 1990.

The catheters associated with K896729 are essentially the same product as the subject device, GentleCath™ Intermittent Urinary Catheter. The key difference between the products listed in K896729 and those covered within this submission are the materials of construction, namely the use of DEHT plasticizer as opposed to DEHP.

The following table compares the similarities and differences between the subject, GentleCath™ Intermittent Urinary Catheter, and the predicate devices, GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (ref; K140953, determined substantially equivalent on 1st August 2014) and Self-Cath® Intermittent Urinary Catheter (ref; K100878, determined substantially equivalent on 26th May 2010) and outlines the product characteristics and specifications which form the basis of the substantial equivalence discussion.

The intended use, technological characteristics and principles of operation of the GentleCath™ Intermittent Urinary Catheter remains the same as those of the predicate devices.

Parameter	**Subject Device**	**Comparison**			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
FDA Product Code	KOD	KOD	EZD	GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter are classified under the product code “KOD-Catheter, Urological”	Self-Cath® Intermittent Urinary Catheter has been classified under the product code “EZD-Catheter, Straight”, however Coudé tip catheters are also included within submission K100878.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
FDA Classification Regulation	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130	All devices are the same classification Regulation Number.	None.
Regulatory Class	Class II	Class II	Class II	All devices are the same classification.	None.
Intended Use/ Indication for Use	Catheters are intended for routine short term drainage of the bladder. The catheter is inserted through the urethra.	Catheters are intended for routine short term drainage of the bladder. The catheter is inserted through the urethra.	Intended for use in patients requiring bladder drainage as determined by their physician.	All devices are intended for bladder catheterization through the urethra.	Self-Cath® Intermittent Urinary Catheters do not state a usage duration.
Cautions	For single use Discard after use Prescription only	For single use Discard after use Prescription only	For single use Discard after use Prescription only	All devices carry the same cautions.	None.
Method of Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	All devices are sterilized by Ethylene Oxide.	None.
Functional configuration	A tube and connector with funnel	A tube and connector with funnel	A tube and connector with funnel	All devices are to same configuration.	None.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
Tube	PVC material with DEHT plasticizer	PVC material with DEHT plasticizer	PVC material with DEHP plasticizer	GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter are manufactured with the same materials.	Materials for GentleCath™ have been replaced to switch DEHP plasticizer to DEHT. The plasticizer used for the Self-Cath® Intermittent Urinary Catheter is DEHP. The solvent and lubricant used for the manufacture of Self-Cath® Intermittent Urinary Catheter is unknown.
Connector	PVC material with DEHT plasticizer and pigment	PVC material with DEHT plasticizer and pigment	PVC material with DEHP plasticizer		
Solvent	Cyclohexanone	Cyclohexanone	Unknown		
Lubricant for tip end	Pluronic RPE non-ionic surfactant	Pluronic RPE non-ionic surfactant	Unknown		

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
Length (Inches)	Male: 16” Female: 6.5”	Male: 16”	Male: 16” Female: 6” Pediatric: 10”	The length of the male catheters available in all devices is 16”. The length of the female catheters within the for GentleCath™ Intermittent Urological Catheter range and the Self-Cath® Intermittent Urinary Catheter range are both a standard length for female catheters. Lengths in compliance with EN ISO1616:1997.	The Self-Cath® Intermittent Urinary Catheter is available in a specific 10”, CH05 pediatric size. GentleCath™ Male Coudé Olive Tip Intermittent Catheter is only available as a male product.
French/ Charrière (FR/CH) Size	Devices are delivered in CH/FR sizes from CH08 to CH18	Devices are delivered in CH/FR sizes from CH08 to CH18	Devices are delivered in CH/FR sizes from CH05 to CH18	The same FR/CH range is available for GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter.	
Connector color differences between sizes	CH08 - blue CH10 - black CH12 - white CH14 - green CH16 - orange CH18 - red	CH08 - blue CH10 - black CH12 - white CH14 - green CH16 - orange CH18 - red	CH08 - blue CH10 - black CH12 - white CH14 - green CH16 - orange CH18 - red	The same colour coding for the connectors is applied across all products.	None.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
Catheter tube -outer diameter (mm)	CH08 - 2.6 CH10 - 3.33 CH12 - 4.00 CH14 - 4.67 CH16 - 5.33 CH18 - 6.00	CH08 - 2.67 CH10 - 3.33 CH12 - 4.00 CH14 - 4.67 CH16 - 5.33 CH18 - 6.00	CH08 - 2.66 CH10 - 3.29 CH12 - 4.16 CH14 - 4.65 CH16 - 5.37 CH18 - 5.99	The diameters of GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter are the same.	The diameters of the Self-Cath® Intermittent Urinary Catheter can be considered substantially equivalent to the diameter of GentleCath™ products.
Catheter tube -inner diameter (mm)	CH08 - 1.65 CH10 - 2.25 CH12 - 2.65 CH14 - 3.25 CH16 - 3.65 CH18 - 4.30	CH08 - 1.65 CH10 - 2.25 CH12 - 2.65 CH14 - 3.25 CH16 - 3.65 CH18 - 4.30	CH08 - 1.65 CH10 - 2.15 CH12 - 2.60 CH14 - 3.10 CH16 - 3.65 CH18 - 4.30		
Catheter Flow Rate (ml/min)	150.5 to 1403.8 ml/min	148.7 to 1321.5 ml/min	115.1 to 1380.7 ml/min	All products found to comply with the requirements of ASTM F623 -99	GentleCath™ Intermittent Urological Catheter has demonstrated a slightly higher flowrate
Catheter Tensile Properties (N)	67.7 to 207.1 N	60.7 to 203.3 N	60.1 to 152.5 N	The tensile properties of the GentleCath™ Intermittent Urinary Catheter was found to be comparable to that of both predicates for the strength of the tube and connector attachment.	Slightly greater force is needed for disconnection of the tube and connector in the subject device, GentleCath™ Intermittent Urinary Catheter.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
K Dimension (mm)	4.7 to 8.4 mm	5 to 7.9 mm	5 to 8.1 mm	The coudé tip angle of the GentleCath™ Intermittent Urinary Catheter was found to be comparable to that of predicate devices.	The K Dimension of subject device and predicate devices can be considered substantially equivalent.
Tube surface	Uncoated	Uncoated	Uncoated	All devices are uncoated catheters.	None.
Eyelets	Smooth eyelet edges	Smooth eyelet edges	Smooth eyelet edges	All devices have smooth eyelet edges.	None.
Eyelet position	Placed on the right and left side if angled tip of catheter is oriented upwards.	Placed on the right and left side if angled tip of catheter is oriented upwards.	Placed on the right and left side if angled tip of catheter is oriented upwards.	All devices have the same placement of the eyelets.	None.
Eyelet size - width (mm)	CH08 - 1.65 CH10 - 2.25 CH12 - 2.65 CH14 - 3.25 CH16 - 3.65 CH18 - 4.30	CH08 - 1.65 CH10 - 2.25 CH12 - 2.65 CH14 - 3.25 CH16 - 3.65 CH18 - 4.30	CH08 - 0.97 CH10 - 1.09 CH12 - 1.07 CH14 - 1.57 CH16 - 2.18 CH18 - 2.67	The dimension of the GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter eyelets are the same.	The dimension of the Self-Cath® Intermittent Urinary Catheter eyelets are slightly smaller than those of the GentleCath™ products.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
Eyelet size - length (mm)	CH08 - 2.50 CH10 - 3.40 CH12 - 3.70 CH14 - 4.35 CH16 - 5.40 CH18 - 5.90	CH08 - 2.50 CH10 - 3.40 CH12 - 3.70 CH14 - 4.35 CH16 - 5.40 CH18 - 5.90	CH08 - 2.01 CH10 - 2.89 CH12 - 3.70 CH14 - 4.22 CH16 - 4.48 CH18 - 5.03	The dimension of the GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter eyelets are the same.	The dimension of the Self-Cath® Intermittent Urinary Catheter eyelets are slightly smaller than those of the GentleCath™ products.
Tip end	Angled (without ball)	Angled (with ball)	Angled (without ball)	All devices include an angled tip variant.	GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter is the only device that has a ball (Olive) at the end of the catheter.
	Straight (without ball)	N/A	Straight (without ball)	The GentleCath™ Intermittent Urological Catheter and Self-Cath® Intermittent Urinary Catheter are both available in a straight tip variant.	The GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter is only available in an angled tip.

Parameter	Subject Device	Comparison			
	GentleCath™ Intermittent Urological Catheter	**Primary Predicate:** GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter (K140953)	**Secondary Predicate:** Self-Cath® Intermittent Urinary Catheter (Coloplast) (K100878)	Similarities	Differences
Coudé indicator	The connector has an indicator which shows the orientation of the coudé tip after insertion into the body	The connector has an indicator which shows the orientation of the coudé tip after insertion into the body	A blue line on the tube shows the orientation of the coudé tip after insertion into the body	The indicator on GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter is on the connector component of the catheter.	The indicator on the Self-Cath® Intermittent Urinary Catheter is located on the tube component of the catheter.
Packaging	Chevron package comprising medical grade paper and film, Corrugated board inner. Corrugated board outer case.	Chevron package comprising medical grade paper and film, Corrugated board inner. Corrugated board outer case.	Peel pack comprises paper and film. Corrugated board inner. Corrugated board outer case.	The same materials are used to package the GentleCath™ Intermittent Urological Catheter and GentleCath™ Male Coudé Olive Tip Intermittent Urinary Catheter.	The Self-Cath® Intermittent Urinary Catheter is packaged in a paper/poly peel pack but the exact materials are unknown.