DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 20, 2016

ConvaTec Limited
Elinor Jones
Regulatory Affairs Specialist
GDC, First Avenue, Deeside Industrial Park
Deeside, Flintshire CH5 2NU
United Kingdom

Re: K161344
Trade/Device Name: GentleCath Glide Intermittent Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: May 10, 2016
Received: August 22, 2016

Dear Elinor Jones:

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,

Joyce M. Whang -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)*
K161344

Device Name
GentleCath Glide Intermittent Catheter

Indications for Use *(Describe)*
Intermittent catheters are indicated for routine transient intermittent drainage of the bladder. The catheter is inserted through the urethra.
GentleCath Glide intermittent catheter is intended for adult use only.

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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ConvaTec

Section 5
510(k) Summary

Applicant: ConvaTec Limited.

Applicant Address: GDC, First Avenue
Deeside Industrial Park
Deeside
Flintshire CH5 2NU
UK

The Establishment Registration number is 1000317571

Contact: Elinor Jones
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Date Prepared: 10 May 2016

Device Identification:

Trade Name: GentleCath Glide 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: GBM

Product Reference: 421565, 421566,421567, 421568, 421571, 421572, 421573, 421574

Predicate Devices:
510(K) number: K000070 Rüsch FloCath Quick

510(k) number: K050874 LoFric Primo

Device Description

A hydrophilic urological catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids from the bladder. The tip/distal end of the tube are inserted into the urethra and the funnel/connector end is used to drain the urine or can be connected to a urine drainage bag. The device is made using Polyolefin Based Synthetic Thermoplastic Elastomer (TPE) as base material with the addition of an additive. The additive material is hydrophilic and makes the surface slippery when wetted with water.

Intended Use

Intermittent catheters are indicated for routine transient intermittent drainage of the bladder. The catheter is inserted through the urethra.
GentleCath intermittent catheters are intended for adult use only.

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) Coefficient of Friction

The laboratory testing shows no differences that would indicate the GentleCath Glide Intermittent Urinary Catheter would be any less safe or effective than the predicate devices. All the parameters are similar or superior for the GentleCath Glide Intermittent Urinary Catheter. Therefore the testing has demonstrated substantial equivalence of the GentleCath Glide 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 have been found to be substantially equivalent; see following pages.

Substantial Equivalence Discussion

The following table compares the similarities and differences between the subject GentleCath Glide Low Friction Intermittent Urinary Catheter and the predicates Rüsch FloCath Quick (ref; K000070) and LoFric Primo (ref; K050874, determined substantially equivalent on May 5 2005) and outlines the product characteristic's and specifications which form the basis of the substantial equivalence discussion.

The intended use, technological characteristics and principles of operation of the GentleCath Glide Low Friction intermittent urinary catheter remains the same as those of the predicate devices.

Parameter	Subject Device			Comparison	
	GentleCath Glide Catheter	Predicate 1 Teleflex: Rüsch FloCath Quick	Predicate 2 Wellspect: Lo-Fric Primo	Similarities	Differences
FDA Product Code	GBM	KOD	GBM	GentleCath Glide and FloCath Quick have been classified as urological catheters.	Lo-Fric Primo has been classified as a urethral catheter.
FDA Classification Regulation	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130	All devices are the same	None
Regulatory Class	Class II	Class II	Class II	All devices are the same	None
Device description	A hydrophilic urinary catheter is a flexible tubular device that is inserted through the urethra and used to pass fluids from the bladder. It includes a substance that makes the surface slippery when it comes into contact with water. The catheter is provided together with a sterile water sachet for lubrication	The Rüsch FloCath catheter consists of a tubular PVC shaft with attached drainage funnel. The catheter is designed with a Nelaton, Olive or Tiemann tip. There are two drainage eyes in various configurations (straight through, staggered, vertical orientated). This device shaft may be uncoated or Hydrogel / Hydrophilic coated. The coating has been tested for both its safety and function.	The **LoFric Primo** Single Use Urinary Catheter is designed as an intermittent pathway for drainage of the bladder. The device consists of a catheter, coated with a hydrophilic low-friction coating. The surface is hydrophilic and when the catheter is activated with the water integrated in the package, it becomes slippery and ready to use. The catheter is provided in a variety of lengths and sizes. The catheter and the activation water is separated, sealed in one bag. By holding the product upright and exerting a light pressure on the folded water pocket, the water will	All devices are developed around the same basic design of a tube with a funnel and two drainage eyes. With surface properties that become hydrophilic when wet.	GentleCath Glide contains an additive within the base material while both FloCath Quick and Lo-Fric Primo have a coating.

			run down and wet the catheter. The bag is opened and the catheter is inserted into the patient's urethra		

Parameter	Subject Device			Comparison	
	GentleCath Glide Catheter	Predicate 1 Teleflex: Rüsch FloCath Quick	Predicate 2 Wellspect: Lo-Fric Primo	Similarities	Differences
Intended use / Indication for Use	Intermittent catheters are indicated for routine transient drainage of the bladder. The catheter is inserted through the urethra. For adult use only.	Rüsch FloCath catheter is flexible tubular device that is inserted through the urethra and is used to pass fluids to or from urinary tracts	The **LoFric** Primo Single Use Urinary Catheter is intended for intermittent catheterization of the urethra	All devices are intended for bladder catheterization through the urethra	GentleCath does not include the intended use of administration of fluids to the bladder, unlike FloCath does
Cautions	Single use Prescription only	Single use Prescription only	Single use Prescription only	All devices are the same	None
Tube Material	POBE	DEHP-free PVC	POBE	The base material of GentleCath Glide is the same as LoFric Primo	FloCath Quick has a different base material to GentleCath Glide and LoFric Primo
Coating/ additive	Additive within the base material	PVP (polyvinyl pyrrolidone)	PVP (polyvinyl pyrrolidone) and sodium chloride	All three devices have surface properties that become hydrophilic and slippery when wet.	The addition of the additive is a different way of achieving a hydrophilic surface from the PVP coating. Biocompatibility studies of the device conclude that the material compound is safe for the intended use.
Connector Material	PVC + DEHT	DEHP-free PVC	POBE	All three connectors are similar in design.	The exact material composition of competitor products is unknown to ConvaTec However, GentleCath Glide funnel is exactly the same as marketed GentleCath male Olive tip K140953

Glue for assembly	Loctite	Not known	Loctite	The glue used to produce LoFric Primo and GentleCath Glide products is exactly the same.	The assembly method used for FloCath Quick is not known to ConvaTec

Parameter	Subject Device			Comparison	
	GentleCath Glide Catheter	Predicate 1 Teleflex: Rüsch FloCath Quick	Predicate 2 Wellspect: Lo-Fric Primo	Similarities	Differences
Biocompatibility	Evaluation and testing within risk management process ISO 10993-1 Cytotoxicity ISO 10993-5 Sensitization ISO10993-10 Skin Irritation ISO10993-10 Genotoxicity ISO10993-3 Subchronic Toxicity ISO 10993-11 EtO sterilization residuals ISO 10993-7	Not known	Not known	The exact biocompatibility tests performed on FloCath Quick and LoFric Primo are not known to Convatec. GentleCath Glide is tested in compliance with ISO 10993-1:2009 for surface devices in contact with mucosal membrane for a limited time period. Genotoxicity and subchronic toxicity are also included due to the prolonged use some patients may be exposed to overtime. Biocompatibility studies of the device conclude that the material compound is safe for the intended use	Not Known
Principal of operation – short description of use	Squeeze water pocket Peel pack open Insert catheter Empty bladder	Squeeze water pocket Hang and let soak for 30sec Peel pack open Insert catheter Empty bladder	Unfold pack Squeeze water pocket Hang and let soak for 30sec Peel pack open Insert catheter Empty bladder	Principal of operation is similar for all three devices	GentleCath Glide does not require soaking before use

	Withdraw catheter Dispose device	Withdraw catheter Dispose device	Withdraw catheter Dispose device		
Length (mm)	Male: 405mm Female: 150-200mm	Male: 400mm Female: 200mm Pediatric: 300mm	Male: 400mm Female: 200mm / 150mm Pediatric: 200mm	Catheter lengths all comply with the requirements of EN1616:1997 Sterile Urethral Catheters for Single Use, Table 1. Shaft dimensions	Some differences in length between the products, but all in compliance with EN1616:1997 Sterile Urethral Catheters for Single Use, Table 1. Shaft dimensions.

Parameter	Subject Device			Comparison	
	GentleCath Glide Catheter	Predicate 1 Teleflex: Rüsch FloCath Quick	Predicate 2 Wellspect: Lo-Fric Primo	Similarities	Differences
FR Size	Male: CH10-CH16 Female: CH10-CH16	Male: CH08-CH20 Female: CH08-CH20 Pediatric: CH06-CH10	Male: CH08-CH18 Female: CH08-CH18 Pediatric: CH06-CH10	All sizes of GentleCath Glide are included within the ranges of the predicate devices	Predicate devices have a bigger size range. GentleCath Glide is being initially launched with a smaller size range.
Connector color indicating size	CH10: Black CH12: White CH14: Green CH16: Orange	CH06: green CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red CH20: Yellow	CH06: green CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red	Connector colour coding all comply with ISO 8836:2007 Suction catheters for use in the respiratory tract : Table 1	None
Catheter tube - outer diameter (mm)	CH10: 3.33 CH12: 4.00 CH14: 4.67 CH16: 5.33	CH06: 2.00 CH08: 2.67 CH10: 3.33 CH12: 4.00 CH14: 4.67 CH16: 5.33	CH06: 2.00 CH08: 2.67 CH10: 3.33 CH12: 4.00 CH14: 4.67 CH16: 5.33	Catheter outer diameters all comply with the requirements of EN1616:1997 Sterile Urethral Catheters for Single Use, Table 2.	Predicate devices have a bigger size range. GentleCath Glide is being initially launched with a smaller size range.

		CH18: 6.00	CH18: 6.00		
Eyelets	Smooth eyelet	Gently rounded catheter eyes which are vertically cut and heat polished	Smooth catheter eyes	All three eyelets are similar in design.	None
Eyelet position	Staggered	Staggered	Staggered	All three eyelets are similar in design.	None

Parameter	Subject Device			Comparison	
	GentleCath Glide Catheter	Predicate 1 Teleflex: Rüsch FloCath Quick	Predicate 2 Wellspect: Lo-Fric Primo	Similarities	Differences
Tip types in range	Nelaton Tiemann/Coude	Nelaton Tiemann/Coude	Nelaton Tiemann/Coude	All three product ranges include the same tip shapes	Predicate devices also have a range of tiemenn/Coude tip shapes.
No-touch functionality	Sleeve	Sleeve	Sleeve	GentleCath Glide is similar to FloCath Quick	LoFric primo is different in that the sleeve is part of the packaging and not a standalone accessory
Liquid for wetting	Sterile water	0.9% Sterile saline solution	Sterile water	GentleCath Glide is similar to LoFric Primo	GentleCath Glide is different from FloCath Quick
Sticky-dot	Double sided adhesive dot	Double sided adhesive dot	Glue blob	GentleCath Glide is similar to FloCath Quick	LoFric Primo is different in that the sticky dot is a glue dot.
Primary packaging	Paper and film peel pack	Paper and film peel pack	Polyethylene with a PET/PE/Aluminium water sachet	GentleCath Glide is similar to FloCath Quick	LoFric Primo is different in that its primary packaging is made from polyethylene.
Secondary packaging	Corrugated board, Box quantity: 30	Corrugated board, Box quantity: 30	Corrugated board, Box quantity: 30	All three product are packed in similar boxes	None
Shipper case	Corrugated board	Corrugated board	Corrugated board	All three product are packed in similar shipper	None
Sterilization process	EO	EO	Radiation	GentleCath is similar to FloCath quick	LoFric primo uses a different sterilization method.
Shelf life	18 months	5 years	Unable to obtain		GentleCath Glide has a

					shorter shelf life which will be extended as real-time and additional accelerated stability information becomes available to support.