June 22, 2022

ConvaTec Limited
Louise Hollywood
Principal Regulatory Affairs Specialist
GDC, First Avenue, Deeside industrial Park
Deeside, Flintshire CH5 2NU
United Kingdom

Re: K213283
Trade/Device Name: GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: May 11, 2022
Received: May 23, 2022

Dear Louise Hollywood:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213283

Device Name
GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter

Indications for Use *(Describe)*
Intermittent drainage of the urinary bladder of Adults who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system

The target population for GC Air for Men is male adults and includes Transitional Adolescents B (18 year old to less than 22 years old but treated like adult).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
Traditional 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92 (c).

Submitted by: ConvaTec Limited.
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Date of Summary: 22 June 2022

Trade Name: GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter

Common Name: Catheter, urethral

Regulation Name: Urological Catheter and accessories

Regulation Number: 21 CFR 876.5130

Classification: Class II

Product Code: GBM (catheter, urethral)

Panel: Gastroenterology and Urology

Predicate Device: GentleCath Glide Intermittent Catheter, K181206

The predicate device has not been subject to a design related recall

Device Description:

GC Air for Men is a sterile, single use, disposable, hydrophilic, intermittent, urethral catheter. It is designed for portability, ease of use and discreet disposal, with *FeelClean*™ technology for superior comfort and less sticky residue. The catheter comprises of a flexible tube and color-coded funnel, both made from plastic materials (Polyvinyl Chloride; PVC). The catheter tube is made using thermoplastic elastomer (TPE) with a hydrophilic additive in the base material which when wetted activates and lubricates the catheter.

Catheters are individually packed into a sealed foil primary pouch along with a sterile (E-Beam) water sachet and handling sleeve, prior to secondary and tertiary packing and sterilization by X-Ray irradiation. The water sachet is provided for wetting of the hydrophilic surface and is burst at the point of use. The handling sleeve is provided to minimize touching the catheter shaft directly during insertion and retraction. The following product sizes and tips are available:

- Size: CH08/10/12/14/10/16/18
- Tips: Nelaton/straight or Coudè /Tiemann
- Effective Length: 405mm

Intended use:

To provide an intermittent pathway for drainage of fluids from the urinary bladder. The catheter is inserted through the urethra.

Indication for Use

Intermittent drainage of the urinary bladder of Adults who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system.

The Intended use population

Adult males who need assistance with bladder drainage due to conditions causing dysfunction of the urinary system.

The target population for GC Air for men is male adults and includes Transitional Adolescents B (18-year-old to less than 22 years old but treated like adult). The selection of the CH size of the catheter is based on the size of the patient and is prescribed by a health care professional. The length of the catheter meets the requirements of EN ISO 20967:2018 for the minimum effective shaft length (275 mm) for males.

Additional users are healthcare professionals including nurses, and/or caregivers and family members who help patients with catheterization.

GC Air for Men target users will be those who are able self-catheterize and have no or minimal dexterity impairment. However, users with dexterity impairments are not excluded from the intended users should they wish to use the device with assistance from others.

Performance Testing: Performance testing for GC Air for Men was conducted per applicable sections of voluntary and FDA consensus standards:

- Sterilization validation was performed by conducting dose setting per ISO 11137-1:2015
- Biocompatibility testing (Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity and Subacute/Subchronic Systemic Toxicity) according to ISO 10993-1:2018 and FDA Guidance "Use of International Standard ISO 10993-1" (2020)
- Sterile packaging in accordance with ISO 11607-1 2019 and ISO 11607-2 2019
- Accelerated and Real Time aged shelf life testing according to ASTM F1980-16
- Performance Testing of Shipping Containers and Systems according to ASTM D4169-16
- Packaging integrity testing according to ASTM F2096-11
- Flow rate and Tensile testing performed in accordance with ISO 20696:2018
- Coefficient of friction according to ASTM D1894:2014
- Tensile testing in accordance with ISO 20696:2018

Conclusion: The performance and biocompatibility testing demonstrate that the GC Air for Men poses no additional risk to safety and efficacy than the predicate device GC Glide. All the parameters are similar for the GC Air for Men; therefore, the GC Air for Men is determined to be substantially equivalent to the predicate device.

Substantial Equivalence discussion

The following table compares the similarities and differences between the subject GC Air for Men and the predicate GC Glide 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 GC Air for Men remains the same as those of the predicate device.

Table 1:Device Comparison Table

Parameter	**Subject Device**	**Predicate Device (K181206)**	**Comparison**	
	GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter	**GentleCath Glide Intermittent Catheter (Adult male product variants only)**	**Similarities**	**Differences**
FDA Product Code	GBM	GBM	All devices are the same	None
FDA Classification Regulation	21 CFR 876.5130	21 CFR 876.5130	All devices are the same	None
Regulatory Class	Class II	Class II	All devices are the same	None
Device description	A sterile, single use, disposable, hydrophilic, intermittent urethral catheter. It is designed for portability, ease of use and discreet disposal with *FeelClean*™ technology for superior comfort and less sticky residue. The catheter comprises of a flexible tube and color coded funnel, both made from plastic materials (Polyvinyl Chloride; PVC). The catheter tube is made using thermoplastic elastomer (TPE) with a hydrophilic additive in the base material which when wetted activates and lubricates the catheter	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 devices are equivalent	GC Air for Men is designed for portability, ease of use and discreet disposal. The catheter is comprised of equivalent materials, including a hydrophilic additive.

Intended use / Indication for Use	To provide an intermittent pathway for drainage of fluids from the urinary bladder. The catheter is inserted through the urethra. For Male adult use including Transitional Adolescents B	Intermittent catheters are indicated for routine transient drainage of the bladder. The catheter is inserted through the urethra. For adult use including Transitional Adolescents B	All devices are the same	Glide is available for male, female adults as well as pediatrics (Children, adolescents, and transitional adolescents B). Device comparison is being made on predicate adult, male variants only. Air is for Adult males only
Cautions	Single use Prescription only	Single use Prescription only	All devices are the same	None
Tube Material	TPE hydrophilic M6906-02 (Polyolefin Based Synthetic Thermoplastic Elastomer (TPE) M6504 as a base material and Techsurf™ 15560 for hydrophilic additive)	TPE hydrophilic M6906-01 (Polyolefin Based Synthetic Thermoplastic Elastomer (TPE) M6504 as a base material and Techsurf™ 15560 for hydrophilic additive)	All devices are equivalent	A different but equivalent hydrophilic additive in the granulate used for the extrusion of the catheter tube is used in the subject device compared to the cleared predicate. The formulation change does not alter the chemical or physical properties of the medical device in its final finished form.
Funnel Material	PVC + DEHT	PVC + DEHT	All devices are the same	None
Glue for assembly	Loctite	Loctite	All devices are the same	None

Biocompatibility	• Evaluation and testing within risk management process ISO 10993-1 • Cytotoxicity ISO 10993-5 • Sensitization ISO10993-10 • Skin Irritation ISO10993-10 • Sensitization ISO10993-10 • Skin Irritation ISO10993-10	• 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	All devices are the same	Biological equivalency between GC Glide and GC Air for Men was established by providing evidence of Material Equivalency through Chemical and Physical Equivalency as well as endpoint equivalency
Principal of operation – short description of use	Squeeze water pocket Peel pack open Insert catheter Empty bladder Withdraw catheter Dispose device	Squeeze water pocket Peel pack open Insert catheter Empty bladder Withdraw catheter Dispose device	All devices are the same	None
Length (mm)	Male: 405mm	Male: 405mm	All devices are the same	None
FR Size	Male: CH08-CH16	Male: CH08-CH18	All devices are the same	Glide is available for male, female adults as well as pediatrics (Children, adolescents, and transitional adolescents B). Device comparison is being made on predicate adult, male variants only. Air is for Adult males only
Funnel color indicating size	CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red	CH08: Blue CH10: Black CH12: White CH14: Green CH16: Orange CH18: Red	All devices are the same	None

Catheter tube - outer diameter (mm ±0.33)	CH08: 2.67 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	All devices are the same	None
Eyelets	Smooth eyelet	Smooth eyelet	All devices are the same	None
Eyelet position	Staggered	Staggered	All devices are the same	None
Tip types in range	Straight / Nelaton Tiemann / Coudè	Straight / Nelaton Tiemann / Coudè	All devices are the same	None
No-touch functionality	Sleeve	Sleeve	All devices are the same	None
Liquid for wetting	Sterile water	Sterile water	All devices are the same	None
Sticky-dot	Double sided adhesive dot	Double sided adhesive dot	All devices are the same	None
Primary packaging	a three-sided seal bag with zipper, composed of 12PET/ADH/LLDPE60 material	Paper and film peel pack	Devices are different	GC Air for men is packed in foil pack that is suitable for X- Ray sterilization. GC Glide is packed in a paper film peel pack that is suitable for EO sterilization.
Secondary packaging	Corrugated board, Box quantity: 30	Corrugated board, Box quantity: 30	All devices are the same	None
Shipper case	Corrugated board	Corrugated board	All devices are the same	None
Sterilization process	X-Ray	EO	Devices are different	Devices are sterilized by different methods, but both achieve a SAL of 10^{-6}
Shelf life	18 Months	18 months	All devices are the same	None