January 25, 2024

ConvaTec
Kim Jones
Senior Regulatory Affairs Specialist
First Avenue, Deeside Industrial Park
Deeside
Flintshire, CH5 2NU
United Kingdom

Re: K232665
Trade/Device Name: GentleCath Air for Women (CH10); GentleCath Air for Women (CH12); GentleCath Air for Women (CH14)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: December 26, 2023
Received: December 26, 2023

Dear Kim 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica K. Nguyen -S

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.

Submission Number *(if known)*

K232665

Device Name

GentleCath Air for Women (CH10);
GentleCath Air for Women (CH12);
GentleCath Air for Women (CH14)

Indications for Use *(Describe)*

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

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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510(k) Summary

Date Prepared	24-Jan-2024
Submitter	ConvaTec, Ltd. First Avenue Deeside Industrial Park Deeside Flintshire CH5 2NU
Contact person	Kim Jones +44 7590333564 kim.jones@convatec.com
Name of Device	GentleCath Air for Women (CH10); GentleCath Air for Women (CH12); GentleCath Air for Women (CH14)
Common Name	Catheter, Straight
Product Code	EZD
Classification	Class II
Regulation Number	2 1 CFR 876.5130
Regulation Name	Urological catheter and accessories.
Primary Predicate Device	GentleCath Glide Intermittent Catheter (K181206)
Recalls	No design related recalls have been submitted for the predicate device GentleCath Glide (K181206)
Purpose of Submission	New Submission
Device Description	GentleCath Air for Women is a sterile, single use, disposable, hydrophilic, intermittent urethral catheter. A urethral catheter is a tubular device intended for being introduced into the urinary bladder through the urethra in order to provide drainage of the bladder. 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. GentleCath Air for Women is designed for portability, ease of use and discreet disposal. Catheters are individually packed and are wetted ready for use upon removal from the case. Catheters are available in the following product sizes: CH10, 12, and 14.
Indications for Use	Intermittent drainage of the urinary bladder of females who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system.
Performance Data	Performance testing for GC Air for Women was conducted per applicable sections of voluntary and FDA consensus standards. • Sterilzation Validation was performed by conducting dose setting per ISO 11137-1:2015 A2: 2019

	• Biocompatibilituy testing (cytotoxicity, Irritiation Sensitization and Checmical Charachterization) accodording to ISO-10993-1:2018 and FDA Guidance "Use of International Standards ISO 10993-1" 2020 • Sterile packaging in accordance with ISO-11607-1: 2019 and 11607-2:2019 • Accelerated Real Time aged shelf-life testing according to ASTM F1980-16 • Performance testing of Shipper Containers and Systems according to ASTM D4169-22 • Package integrity testing according to ASTM F2096-11 • Tensile testing performed in accordance with ISO 20696:2018 • Flow Rate testing performed in accordance with ISO 20696:2018 • Coefficient of friction according to ASTM D1894:2014
Technological Comparison	Hydrophilic Intermittent Urinary Catheters is the intended technological principle for both the subject and predicate devices. It is based on the use to provide an intermittent pathway for the drainage of urine from the urinary bladder. The catheter is inserted through the urethra At a high level GentleCath Glide (predicate), GentleCath Air for Men (reference) and GentleCath Air for Women (subject). Are based on the following same technological elements: • Indications for Use • To drain the bladder on an intermittent basis as required via the urethra • Hydrophilic catheter Catheter tube has rounded tip and rounded eyelets a • All materials biocompatible for contact with the urethra and urine over cumulative use • GentleCath Air for Men (reference) and GentleCath Air for Women (subject) are sterilized by X-ray • Single Use The following technological difference exists between the subject and the predicate devices: • A sterile 'Air Case' that houses the catheter, funnel and wetting mechanism • Discreet disposal • Wetting chamber which wets catheter surface on withdrawal • compact primary pack designed to look like a cosmetic product The differences in technological characteristics do not raise different questions of safety and effectiveness.

Conclusion	The data information provided in this submission support the conclusion that GentleCath Air for Women (K232665) is substantially equivalent in safety and performance to the predicate device (K181206).

escription	Subject Device	Primary Predicate Device	Reference Device	Comparison
Name	GentleCath Air for Women	GentleCath Glide	GentleCath Air for Men	N/A
Manufacturer	Convatec	Convatec	Convatec	Same
510(k) Clearance	Subject of this submission	K181206	K213283	N/A
Prescription/Over-the-Counter Use	Prescription Use	Prescription Use	Prescription Use	Same
Product Code	EZD	GBM	GBM	Same
Classification Regulation	876.5130 – Urological catheter and accessories	876.5130 – Urological catheter and accessories	21 CFR 876.5130 – Urological catheter and accessories	Same
Classification	II	II	II	Same
Indications for Use	Intermittent drainage of the urinary bladder of females who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system.	Intermittent drainage of the urinary bladder of those who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system	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.	Same. The subject device is indicated for use in females. The predicate device and reference device are indicated for use in females and males.
Tube Material	Hydrophilic TPE	Hydrophilic TPE	Hydrophilic TPE	Same
Funnel Material	HDPE + EVA	PVC + DEHT	PVC + DEHT	Substantially equivalent. The material difference does not raise different questions of safety and effectiveness than the predicate device.
Effective Length	90mm	140mm	140mm	Substantially equivalent. The difference in catheter length does not raise different questions of safety and effectiveness than the predicate device.
Catheter Tube Outer Diameter (mm)	CH10 3.3 CH12 4.0 CH14 4.7	CH10 3.3 CH12 4.0 CH14 4.7	CH10: 3.3 CH12: 4.0 CH14: 4.7	Same. *The predicate and reference device include additional catheter tube outer diameters.
Eyelets	2 Smooth eyelets on opposite sides	2 Smooth eyelets on opposite sides	2 Smooth eyelets on opposite sides	Same
Tip Type	Straight / Nelaton	Straight / Nelaton	Straight / Nelaton	Same. *The predicate and reference device include additional catheter tip types.
Use Type	Single use	Single use	Single use	Same

escription	Subject Device	Primary Predicate Device	Reference Device	Comparison
Primary Packaging	Discreet carry housing with water reservoir	Pouch with water sachet	Pouch with water sachet	Substantially equivalent. The packaging difference does not raise different questions of safety and effectiveness than the predice device.
Sterilization	X-Ray SAL: 10^{-6}	Ethylene Oxide SAL: 10^{-6}	X-Ray SAL: 10^{-6}	Substantially equivalent. The subject device uses the same sterilization method as the reference device