April 1, 2026

Convatec Limited
Danielle Gibboney
Sr. Regulatory Affairs Specalist
First Avenue
Deeside Industrial Park
Deeside Flintshire, GB CH5 2NU
United Kingdom

Re: K252943
Trade/Device Name: GentleCath™ Air for Men; GentleCath™ Glide Intermittent Catheter; GentleCath™ Air for Women
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: March 2, 2026
Received: March 2, 2026

Dear Danielle Gibboney:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252943

Device Name
GentleCath™ Air for Men
GentleCath™ Glide Intermittent Catheter
GentleCath™ Air for Women

Indications for Use *(Describe)*
GentleCath™ Air for Men: 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.

GentleCath™ Glide Intermittent Catheter: Intermittent drainage of the urinary bladder of adults and pediatric patients who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system.

GentleCath™ Air for Women: 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	April 1, 2026
Submitter	Convatec Limited First Avenue DEESIDE INDUSTRIAL PARK Deeside Flintshire, GB CH5 2NU
Contact Person	Danielle Gibboney Sr. Regulatory Affairs Specialist E-mail: danielle.gibboney@convatec.com
Name of Device	GentleCath™ Air for Men, GentleCath™ Glide Intermittent Catheter, GentleCath™ Air for Women
Device Common Name	Catheter, Urethral
Device Product Code	EZD
Classification Name	Urological catheter and accessories
Device Classification	Class II
Classification Regulation	21 CFR 876.5130
Predicate Devices	GentleCath Air for Men (K213283) GentleCath Glide Intermittent Catheter (K181206) GentleCath Air for Women (K232665)
Device Description	The subject intermittent catheters are the same or slightly modified from the predicate catheters with additional claims included for the specific hydrophilic surface technology (FeelClean™ Technology) used for these catheters. These devices are sterile, single-use, hydrophilic intermittent urinary catheters intended for bladder drainage in patients requiring intermittent catheterization. All three devices share the same fundamental intended use and technological characteristics as described in their respective cleared submissions.
Indications for Use	GentleCath Air for Men: 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.

	GentleCath Glide Intermittent Catheter: Intermittent drainage of the urinary bladder of adults and pediatric patients who need assistance with drainage due to conditions causing urinary retention or dysfunction of the urinary system. GentleCath Air for Women: 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.
Technological Comparison	The subject device is substantially equivalent to the identified predicate device(s) with respect to intended use, design, technological characteristics, and performance. The modifications described in this submission, including the proposed additional claims for FeelClean™ Technology, do not alter the fundamental scientific technology or raise different questions of safety or effectiveness. Refer to Table 1 for a detailed technological comparison between the subject and predicate catheters.
Performance Data	Non-clinical testing and clinical information were provided to support the proposed claims for the FeelClean™ Technology and modifications to the predicate devices, including (1) *in vitro* and *ex vivo* coefficient of friction testing and insertion/withdrawal force testing for the friction force and lubricity claims; (2) a post-market study including patient comfort questionnaires for the comfort claim; (3) sterilization validation on the proposed sterilization method change and prolonged stability testing to support the proposed shelf life extension. The proposed modifications do not significantly affect the safety or effectiveness of the device, and the devices are substantially equivalent to their predicate devices.
Conclusion	The data and information provided in this submission support that the subject device (including GentleCath™ Air for Men, GentleCath™ Glide Intermittent Catheter, and GentleCath™ Air for Women) is substantially equivalent in safety and performance to the predicate devices cleared under K213283, K181206, and K232665.

Table 1: Substantial Equivalence Comparison Table

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
Name of Device	GentleCath Air for Men GentleCath Glide Intermittent Catheter GentleCath Air for Women	GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter	GentleCath Glide Urinary Intermittent Catheter	GentleCath Air for Women	N/A
510(k)	K252943	K213283	K181206	K232665	N/A
Product Code	EZD	GBM	GBM	EZD	N/A
Device Classification	Class II	Class II	Class II	Class II	Same
Device Regulation	21 CFR 876.5130	21 CFR 876.5130	21 CRF 876.5130	21 CFR 876.5130	Same
Intended Use/Indications for Use	GentleCath Air for Men: 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. GentleCath Glide Intermittent Catheter: Intermittent drainage of the urinary bladder of adults and pediatric patients who need assistance with drainage	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.	Intermittent Catheters are indicated for routine transient intermittent drainage of the bladder. The catheter is inserted through the urethra.	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.	Similar. The subject device includes all 3-predicate devices into one submission. The indications for use of GentleCath Air for Men and GentleCath Air for Women remain unchanged from their predicate device. The language of the

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
	due to conditions causing urinary retention or dysfunction of the urinary system. GentleCath Air for Women: 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.				indications for use of GentleCath Glide is modified to align with the indications of GentleCath Air for Men and GentleCath Air for Women.
Tube Material	GentleCath Air for Men: Hydrophilic Thermoplastic Elastomer (TPE) GentleCath Glide Intermittent Catheter: Hydrophilic TPE GentleCath Air for Women: Hydrophilic TPE	Hydrophilic TPE	Hydrophilic TPE	Hydrophilic TPE	Same. The subject device includes all 3-predicate devices into one submission. They all have the same tube material.
Funnel Material	GentleCath Air for Men: Polyvinyl chloride (PVC) + Di(2-ethylhexyl) terephthalate (DEHT) GentleCath Glide Intermittent Catheter: PVC + DEHT	PVC + DEHT	PVC + DEHT	HDPE + EVA	Slightly Different. In K252943, the raw material of the HDPE used in GentleCath Air for Women does not include a specific additive present in the formulation of the

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
	GentleCath Air for Women: High-Density Polyethylene (HDPE) + Ethylene-vinyl acetate (EVA)				HDPE raw material for the predicate device (K232665). Removal of trace amount of specific additive from the funnel raw material formulation would not change the device performance or biocompatibility profile.
Length	GentleCath Air for Men: 405mm GentleCath Glide Intermittent Catheter: Male: 405mm Female: 150-200mm GentleCath Air for Women: 90mm	405 mm	Male: 405mm Female: 150-200mm	90mm	Same
Catheter Tube Outer Diameter (mm)	GentleCath Air for Men: CH08-CH16 GentleCath Glide Intermittent Catheter: Male: CH08-CH18 Female: CH08-CH16 GentleCath Air for Women: CH10-CH14	CH08-CH16	Male: CH08-CH18 Female: CH08-CH16	CH10-CH14	Same

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
Eyelets	GentleCath Air for Men: 2 Smooth eyelets on opposite sides GentleCath Glide Intermittent Catheter: 2 Smooth eyelets on opposite sides GentleCath Air for Women: 2 Smooth eyelets on opposite sides	2 Smooth eyelets on opposite sides	2 Smooth eyelets on opposite sides	2 Smooth eyelets on opposite sides	Slightly Different. For CH10, CH12, CH14, and CH16 catheters, the eyelet's tolerance has been changed from ±0.2 mm to ±0.3 mm in K252943. The slight dimensional tolerance change to eyelets at the tip of the catheter tubes would not change the device performance.
Tip Type	GentleCath Air for Men: Straight GentleCath Glide Intermittent Catheter: Straight or Coudé GentleCath Air for Women: Straight	Straight	Straight or Coudé	Straight	Same. Each catheter tip type is equivalent to their predicate tip type.
Use Type	GentleCath Air for Men: Single Use GentleCath Glide Intermittent Catheter: Single Use GentleCath Air for Women: Single Use	Single Use	Single Use	Single Use	Same

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
FeelClean Technology™	GentleCath Air for Men: Yes. GentleCath Glide Intermittent Catheter: Yes. GentleCath Air for Women: Yes.	Yes	Yes	Yes	Same. This submission includes additional claims regarding the FeelClean Technology™.
Sterilization	GentleCath Air for Men: X-Ray SAL: 10^{-6} GentleCath Glide Intermittent Catheter: X-Ray SAL: 10^{-6} GentleCath Air for Women: X-Ray SAL: 10^{-6}	X-Ray SAL: 10^{-6}	ETO SAL: 10^{-6}	X-Ray SAL: 10^{-6}	Different. GentleCath Glide was sterilized using ETO previously in ***K181206***, but it is changed to X-ray sterilization in K252943. The change is to adopt the X-Ray method used for another device in the product family, GentleCath Air for Men (cleared in K213283) with a maximum sterilization dose of 44.3 kGy.