November 26, 2024

Coloplast Corp
Vallabha Tantry
Senior Regulatory Specialist
1601 West River Road North
Minneapolis, Minnesota 55441

Re: K242049
Trade/Device Name: SureCath Set
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: July 12, 2024
Received: October 30, 2024

Dear Vallabha Tantry:

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.

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
OHT3: Office of Gastrorenal, ObGyn,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242049

Device Name

SureCath Set

Indications for Use *(Describe)*

The product is intended for use in male, female, and pediatric patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

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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TRADITIONAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Vallabha Tantry Sr. Regulatory Affairs Specialist Coloplast 1601 West River Road North Minneapolis MN 55411 Phone: +1 (612)-806-1798 Email: usvtan@coloplast.com
Date of Summary:	July 12, 2024
Subject Device:	
Trade or Proprietary Name:	SureCath Set
Item/Model Numbers:	28012, 28013, 28001, 28002, 28003, 28004, 28014, 28005 / 28005S, 28006 / 28006S, 28007 / 28007S, 28008 / 28008S, 28009 / 28009S, 28010, 28017, 28018, 28019, 28026 / 28026S, 28027 / 28027S, 28028 / 28028S, 28029 / 28029S
Common Name:	Urological catheter and accessories
Regulation/Classification Name:	Gastroenterology and Urology
Regulation Number:	21 CFR 876.5130
Product Code:	EZD

Review Panel:	Gastroenterology/Urology
Predicate Device: **Reference Device:**	K973090, Conveen EasiCath Set. The predicate device has not been subject of a design-related recall. K221401, Self-Cath and Self-Cath Plus The reference devices have not been subject to a design-related recall.
Device Description:	SureCath Set is a sterile, single-use hydrophilic coated intermittent catheter with integrated urine bag. An ampoule of saline solution is provided inside the urine bag. This saline solution from the ampoule is poured over the catheter to activate the coating before use.
Indications for Use:	The product is intended for use in male, female, and pediatric patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Technological Characteristics Comparison

The table below summarizes the technological characteristics of SureCath Set as compared to the predicate device.

Parameter	**Subject device**	**Predicate device**	**Reference Device**
	SureCath Set	**Conveen EasiCath Set**	**Self-Cath and Self-Cath Plus**
510(k) Number	Unassigned	K973070	K221401
Regulation Name	Gastroenterology and Urology	Gastroenterology and Urology	Gastroenterology and Urology
Regulation Number	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130
Product Code	EZD	EZD KNX	EZD (Self-Cath) EZL (Self-Cath Plus)
Classification	II	II	II

Parameter	Subject device	Predicate device	Reference Device
	SureCath Set	**Conveen EasiCath Set**	**Self-Cath and Self-Cath Plus**
Prescription Device	Yes	Yes	Yes
Intended Use	Intermittent catheterization through the urethra.	Intermittent catheterization through the urethra.	The product is intended for intermittent catheterization through the urethra
Indications for Use	The product is intended for use in male, female, and pediatric patients requiring bladder drainage as determined by their physician. This device is indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.	The Conveen EasiCath Set is indicated for use by patients for intermittent Catherization for the purpose of bladder drainage.	**Self-Cath** and **Self-Cath Plus** are intended for use in male, female, and pediatric patients (neonates, infants, children, adolescents, and transitional adolescents) requiring bladder drainage as determined by their physician. The devices are indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.
Condition of Use	Intermittent use and single use	Same	Same
Device Categorization per ISO 10993	Surface contacting device in contact with mucosal membrane for a prolonged duration of time (24 h < t< 30 days)	Same	Same
Sterility	SAL 10^{-6}	Same	Same
Sterilization Method	Ethylene Oxide (EO), Half cycle, Over-kill	Same	Same
Shelf Life	24 months at time of submission (planned 36 months)	36 months	24 months

Parameter	Subject device	Predicate device	Reference Device
	SureCath Set	**Conveen EasiCath Set**	**Self-Cath and Self-Cath Plus**
Catheter Materials	Polyvinyl chloride, DEHT	Polyvinyl chloride, DEHP	Same
Hydrophilic Coating	Polyvinylpyrrolidone (PVP) with DEHT	Polyvinylpyrrolidone (PVP) with DBP	Polyvinylpyrrolidone (PVP) (Self-Cath Plus) None (Self-Cath)
Tip Configuration	Nelaton tip and Tiemann tip	Nelaton tip	Straight tip Olive Coudé tip Tapered Coudé tip
Urine bag material	Polypropylene (PP) (bottom film of the urine bag) Polyethylene (PE)	Same	Not applicable
Ampoule	The product is supplied with an ampoule containing sterile water for lubrication of the catheter. The ampoule is placed inside the urine bag.	Same	None
Connector	Polyvinyl chloride (PVC) compound containing different masterbatch colours and Bis(2-ethylhexyl) terephthalate plasticizer (DEHT)	Polyvinyl chloride (PVC) compound containing different masterbatch colours and DEHP	Polyvinyl chloride (PVC) compound containing different masterbatch colours and Bis(2-ethylhexyl) terephthalate plasticizer (DEHT
Primary Packaging Description	Foil pouch which provides identification of a used product	Same	Same

Parameter	Subject device	Predicate device	Reference Device
	SureCath Set	**Conveen EasiCath Set**	**Self-Cath and Self-Cath Plus**
Packaging Materials	Polyethylene terephthalate (PET) / Polyethylene (PE) Uncoated medical paper	Same	Coated polyolefin Ultra-low-density polyethylene/Ethylene-vinyl acetate
Effective Catheter Length	Male (CH 8 – 18) 34cm / 13.4in Paediatric(CH 8 – 10) 15cm / 5.8 in Female (CH 8 – 16) 15cm / 5.8 in	Same	Male: 14.9 inches (38 cm) Female: 4.8 inches (12 cm) Pediatric (CH05, CH06): 8.0 inches (20 cm) Pediatric (CH08 and CH 10): 8.1 inches (21 cm)

Summary of Non-Clinical Performance Testing

Non-clinical test summary:	Bench performance testing and usability testing were conducted to verify the proposed subject devices met the pre-determined acceptance criteria per specified requirements. Testing was performed on final, finished, and sterilized devices as described in the applicable submission sessions.
Biocompatibility:	ISO 10993-1 :2018, Biological evaluation of medical devices – Part 1: Evaluation of testing within a risk management process
	ISO 10993-5: 2009: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
	ISO 10993-7: 2008: Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10: 2023: Biological evaluation of medical devices – Part 10: Tests for skin sensitization
	ISO 10993-11: 2017: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
	ISO 10993-23: 2021: Biological evaluation of medical devices – Part 23: Tests for irritation
The following biological endpoints were addressed: cytotoxicity, irritation or intracutaneous reactivity, sensitization, material mediated pyrogenicity, acute systemic toxicity, and subacute toxicity.	
Catheter performance:	ISO 20696: 2018, Sterile urethral catheters for single use
	ASTM F623-19, Standard performance specification for Foley Catheter
	Coloplast Test Strength of connection between the catheter and the urine bag
	Coloplast Test Method Aseptic insertion (non-touch approach) of catheter through urine bag
	Coloplast Test Method for water amount of 20 ml in ampoule must activate coating on catheter
	Coloplast Test Method Friction of the coated catheter after 30 seconds activation time
	Coloplast Test Method Tearing and emptying of the urine bag
	Coloplast Test Method Volume of the urine bag
	Coloplast Test Method Strength of the urine bag
	EN/IEC 62366-1:2015/A1:2020 Medical devices — Part 1: Application of usability engineering to medical devices
Bench performance testing and usability testing were conducted to verify the proposed subject devices met the pre-determined acceptance criteria per specified requirements. Testing was performed on final, finished, and sterilized devices as described in the applicable submission sessions.	
Packaging:	ISO 11607-1 :2020, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
	DS EN ISO 20696: 2018, Sterile urethral catheters for single use
	ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
Packaging integrity testing was conducted to verify the maintenance of the sterile barrier through shelf life. Transportation testing was conducted to verify that there is no impact to the device safety or efficacy of the catheter performance due to the hazards associated with the transportation environment.	

Aging:	ASTM F1980-21 Standard guide for accelerated aging of sterile barrier systems and medical devices
The stability study investigated whether there were unexpected (significant) changes in product properties over the shelf-life of the device. The properties meet the acceptance criteria after the aging cycle, the device is therefore deemed to be stable for the defined shelf life.	

Conclusion

The performance testing demonstrates the subject device is as safe and effective as the predicate device.