April 17, 2025

Coloplast Corp
Vallabha Tantry
Sr. Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, Minnesota 55411

Re: K250270
Trade/Device Name: Luja Set
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: March 18, 2025
Received: March 18, 2025

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
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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)*

K250270

Device Name

Luja Set

Indications for Use *(Describe)*

Luja Set is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.
The product is indicated for male patients only (adults and pediatric above the age of 1 years).

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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SPECIAL 510(K) SUMMARY

Submitted by:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Vallabha Tantry Sr. Regulatory Affairs Specialist Coloplast Corp. 1601 West River Road North Minneapolis MN 55411 Phone: +1 (612)-806-1798 Email: usvtan@coloplast.com
Date of Summary:	April 16, 2025

Subject Device:

Trade or Proprietary Name:	Luja Set
Item/Model Numbers:	20071/ 20072/ 20074/ 20076
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:	K241210, Luja Coudé (Sizes CH 8-CH18) The predicate device has not been subject of a design-related recall.
Reference Device:	K222059, SpeediCath Flex Set The reference device has not been subject to a design-related recall.
Device Description:	The medical device is an intermittent, ready-to-use, sterile, hydrophilic-coated catheter with integrated urine bag. It contains a catheter with a flexible tip that facilitates passage through the sphincter in the urethra. The catheter is shielded by a sleeve, which serves as protection from the user's hands during insertion. Several small holes (micro-holes) by the straight tip, create a draining zone, which allow the urine to flow from the bladder out through the catheter to a urine bag. The drainage end of the catheter is attached to a urine bag with a tear off section to open the bag for emptying. The catheter is sterilized by radiation. The Luja Set is available in sizes: CH10, CH12, CH14, and CH16.
Indications for Use:	Luja Set is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The product is indicated for male patients only (adults and pediatric above the age of 1 years).

Technological Characteristics Comparison

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

Parameter	**Subject device**	**Predicate device**
	Luja Set male	**Luja Coudé**
510(k) Number	K250270	K241210
Regulation Name	Urological catheter and accessories	Same
Regulation Number	21 CFR 876.5130	Same
Product Code	EZD	Same
Classification	II	Same
Prescription Device	Yes	Same
Intended Use	Intermittent catheterization through the urethra.	Same
Indications for Use	Luja Set is indicated for use by patients with urine retention and patients with post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The product is indicated for male patients only (adults and pediatric above the age of 1 year).	Same

Parameter	Subject device	Predicate device
	Luja Set male	**Luja Coudé**
Condition of Use	Intermittent use and single use	Same
Drainage	Micro holes	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
Sterility	SAL 10^{-6}	Same
Sterilization Method	e-beam	Same
Shelf Life	2 years	Same
Available Sizes	CH/ FR 10 CH/ FR 12 CH/ FR 14 CH/ FR 16	CH/ FR 8 CH/ FR 10 CH/ FR 12 CH/ FR 14 CH/ FR 16 CH/ FR 18
Catheter Materials	Polyurethane	Same
Hydrophilic Coating	Polyvinylpyrrolidone (PVP) based	Same
Swelling media (Wetting Agent)	Saline solution with PEG	Same
Tip Configuration	Straight tip	Flexible curved tip (bended)
Primary Packaging Description	Single pouch package, dark grey	Single and double-loop pouch packages, dark grey
Packaging	Inner layer: PE-peel	Same

Parameter	Subject device	Predicate device
	Luja Set male	**Luja Coudé**
Materials	Outer layer: Printed PETP	Same
Effective Catheter Length	Effective length (according to ISO 20696:2018): 33cm (13 inches)	Same
Inner Connector	Polyurethane White	Same
Outer Connector	2 shot components: 1st shot: Polypropylene 2nd shot: Thermoplastic elastomer	Same
Handle	2 shot components: 1st shot: Polypropylene 2nd shot: Thermoplastic elastomer	Same
Cap	2 shot components: 1st shot: Polypropylene 2nd shot: Thermoplastic elastomer	Polypropylene
Bag Connector	LLDPE - Linear Low Density Polyethylene	N/A
Collection Bag	(LDPE) LDPE/CO-PE-PP/LDPE – Low Density Polyethylene/ Polyethylene-Polypropylene copolymer/ Low Density Polyethylene	N/A

Summary of Non-Clinical Performance Testing

Non-clinical test summary:	The subject device when compared to the predicate (K241210) device shares similar technological characteristics as summarized in the technological characteristics table. The subject device differs from the predicate device in the straight tip configuration and the urine bag. Testing conducted with the predicate and reference device was deemed applicable to the subject device. Risk assessment was conducted, and two performance risks were identified: flow rate and kink stability. To support the flow rate and kink stability testing, the SpeediCath Flex Set (K222059) was used as a reference device.
Catheter performance:	ISO 20696: 2018, Sterile urethral catheters for single use
	ASTM F623-19, Standard performance specification for Foley Catheter
Bench performance testing was 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.	

Conclusion

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