October 28, 2026

Coloplast Corp.
Vallabha Tantry
Senior Regulatory Specialist
1601 W. River Rd. N
Minneapolis, Minnesota 55411

Re: K263512
Trade/Device Name: Luja female
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: September 29, 2026
Received: September 29, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

BONHYE KOO -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K263512

Please provide the device trade name(s).

Luja female

Please provide your Indications for Use below.

Luja female is indicated for use by patients with urine retention and patients with a 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 female patients only (adults and children of and above the age of 2 years).

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

SPECIAL 510(K) SUMMARY

Submitted by:

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Date of Summary: October 28, 2026

Subject Device:

Trade or Proprietary Name:	Luja female
Model Numbers:	20046, 20048
Common Name:	Intermittent Urinary Catheter
Regulation/Classification Name:	Urological catheter and accessories
Regulation Number:	21 CFR 876.5130
Product Code:	EZD, Catheter Straight
Regulatory Class:	Class II

Review Panel:	Gastroenterology/Urology
Predicate Device:	K241028, Luja female The predicate device has not been subject to a design- related recall.
Reference Device:	K180258, SpeediCath Standard The reference device has not been subject to a design- related recall.
Device Description:	Luja female is a single-use, sterile catheter for intermittent urinary catheterization. The catheter has a tapered conical shape with reduced thickness on two sides of the lower part of the product, to improve handling and reduce weight/material consumption. The device is composed of a sterile catheter inserted in a rigid inner container. The top part of the catheter, which also includes the products sterile sealings, is covered, and sealed by a medium-soft inner handle. The catheter contains several small holes (micro holes) by the tip creating a drainage zone which allows the urine to flow from the bladder through the catheter. The drainage end of the device handle has an outlet to which a urine bag with a suitable connector can be connected. The catheter also contains a hydrophilic-coating and is sterilized by irradiation. The device is intended for home and healthcare use. The primary packaging provides the sterile barrier and contains a proof of seal for identification of opened products. Luja female (20046 & 20048) is available in one effective length (7cm) in the following sizes: CH 6 and CH 8. The reference device supports the Luja female catheter in sizes CH6 & CH8.
Indications for Use:	Luja female is indicated for use by patients with urine retention and patients with a 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 female patients only (adults and children of and above the age of 2 years).

Technological Characteristics Comparison

The table below summarizes the technological characteristics of Luja female as compared to the predicate and reference devices.

Parameter	Subject device	Predicate device
	Luja female	**Luja female**
510(k) Number	K263512	K241028
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 female is indicated for use by patients with urine retention and patients with a 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 female patients only (adults and children of and above the age of 2 years).	Same
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

Parameter	Subject device	Predicate device
	Luja female	**Luja female**
Sterility	SAL 10^{-6}	Same
Sterilization Method	e-beam	Same
Shelf Life	2 years	Same
Available Sizes	FR 6 / CH 6 FR 8 / CH 8	FR 10 / CH 10 FR 12 / CH 12 FR 14 / CH 14 FR 16 / CH 16
Catheter Materials	Polyurethane	Same
Hydrophilic Coating	Polyvinylpyrrolidone (PVP) based	Same
Swelling media (Wetting Agent)	Saline solution with PEG	Same
Tip Configuration	Straight (Nelaton)	Same
Primary Packaging Description	Packaging consists of the container, inner handle, and the unibody which are made of polypropylene and polyethylene.	Same
Effective Catheter Length	Effective length (according to ISO 20696:2018): 7 cm (2.8 in)	Effective length (according to ISO 20696:2018): 9cm (3.5 in)

Summary of Non-Clinical Performance Testing

Non-clinical test summary:	The subject device when compared to the predicate (K241028) device shares similar technological characteristics with the exception of the smaller outer diameter (6 & 8 Fr) and shorter effective catheter length (7 cm). Testing conducted with the predicate was deemed applicable to the subject device. Risk assessment was conducted. These risks are mitigated through verification testing.
Catheter performance:	ISO 20696: 2018, Sterile urethral catheters for single use (Outer Diameter, Effective Shaft Length, Catheter Strength, Peak Tensile Force, Flow Rate)
	ASTM D1894-14: Standard test method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting
	Coloplast Test Method Friction at T=0 and T=5 minutes
	Coloplast Test Method catheter rigidity
	Coloplast Test Method pH and osmolality
	Coloplast Test Method micro-hole diameter
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 intended use, indications for use, and technological characteristics of the subject device are substantially equivalent to the predicate device. The non-clinical performance testing demonstrates the subject device is as safe and effective as the predicate device.