July 7, 2026

Coloplast A.S.
Troy Thome
Sr. Regulatory Affairs Specialist
1601 W. River Rd. N.
Minneapolis, Minnesota 55411

Re: K262045
Trade/Device Name: Luja Soft
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: June 17, 2026
Received: June 17, 2026

Dear Troy Thome:

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.

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,

ANDREW M. FALES -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.	K262045

Please provide the device trade name(s).

Luja Soft

Please provide your Indications for Use below.

Luja Soft 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 for adult male patients only.

Please select the types of uses (select one or both, as applicable).	☒ 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:	Coloplast A/S Holtedam1 3050 Humlebaek Denmark
Contact Person:	Troy Thome Sr. Regulatory Affairs Specialist Coloplast Corp. 1601 West River Road North Minneapolis MN 55411 Phone: +1 (612)-356-9917 Email: ustthome@coloplast.com
Date of Summary:	July 2, 2026
Subject Device:	
Trade or Proprietary Name:	Luja Soft
Common Name:	Urological catheter and accessories
Regulation/Classification Name:	Urological catheter and accessories
Regulation Number:	21 CFR 876.5130
Product Code:	EZD

Review Panel:	Gastroenterology/Urology
Predicate Device:	K200142, SpeediCath Soft The predicate device has not been subject of a design- related recall.
Reference Device:	K251116, Luja Coude 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. It contains a catheter with a flexible tip that facilitates passage through the sphincter in the urethra. 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. The catheter is sterilized by radiation. The Luja Soft is available in sizes: CH10, CH12, CH14, and CH16.
Indications for Use:	Luja Soft 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 for adult male patients only.

Technological Characteristics Comparison

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

Parameter	**Subject device**	**Predicate device**	**Reference device**
	Luja Soft	**SpeediCath Soft**	**Luja Coudé**
510(k) Number	K262045	K200142	K251116
Regulation Name	Urological catheter and accessories	Same	Same
Regulation Number	21 CFR 876.5130	Same	Same
Product Code	EZD	Same	Same
Classification	II	Same	Same
Prescription Device	Yes	Same	Same
Intended Use	Intermittent catheterization through the urethra.	Same	Same
Indications for Use	Luja Soft 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 for adult male patients only.	Same	Luja Coudé 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).
Condition of Use	Intermittent use and single use	Same	Same
Drainage	Micro holes	2 eyelet catheter	Micro holes
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	e-beam	Same	Same
Shelf Life	18 months at submission (planned 2 years)	2 years	2 years
Available Sizes	Male, FR 10 / CH 10 Male, FR 12 / CH 12 Male, FR 14 / CH 14 Male, FR 16 / CH 16	Same	Male, FR 8 / CH 8 Male, FR 10 / CH 10 Male, FR 12 / CH 12 Male, FR 14 / CH 14 Male, FR 16 / CH 16 Male, FR 18 / CH 18

Parameter	Subject device	Predicate device	Reference device
	Luja Soft	**SpeediCath Soft**	**Luja Coudé**
Catheter Materials	Polyurethane	Same	Same
Gripper Material	Material: TPE / SEBS Colorant: Grey LLDPE	Material: Same Colorant: Turquoise LLDPE	N/A
Hydrophilic Coating	Polyvinylpyrrolidone (PVP) based	PVP with NMP	Same as subject
Swelling media (Wetting Agent)	Saline solution with PEG	Same	Same
Tip Configuration	Flexible straight tip	Same	Flexible curved tip (bended)
Primary Packaging Description	Top foil and bottom foil welded together	Same	Single and double-loop pouch packages, dark grey
Packaging Materials	Inner layer: PE Outer layer: oriented polyamide (OPA) and aluminum Exterior outer foil color: Grey	Inner/Outer layer: Same Exterior outer foil color: White	Inner layer: PE-peel Outer layer: Printed PETP
Effective Catheter Length	Effective length (according to ISO 20696:2018): 33cm (13 inches)	Same	Same

Summary of Non-Clinical Performance Testing

Non-clinical test summary:	The subject device when compared to the predicate (K200142) device shares similar technological characteristics as summarized in the technological characteristics table. Testing conducted with the predicate and reference device was deemed applicable to the subject device. Risk assessment was conducted and three performance risks were identified: flow rate (per ISO 20696: 2018 and ASTM F623-19), kink stability (per ISO 20696: 2018) and wetting agent pH (internal test method). It was evaluated that the modification to change the eyelet configuration from 2-eyelet to multiple hole eyelets did not introduce new biological concerns.
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.