October 26, 2023

Coloplast Corporation
Troy Thome
Sr. Regulatory Affairs Specialist
1601 West River Road North
Minneapolis, MN 55411

Re: K233101
Trade/Device Name: Luja Coude (20108 Male CH18 - large packaging)
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: September 26, 2023
Received: September 26, 2023

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: 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.

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
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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)*
K233101

Device Name
Luja Coude (20108 Male CH18 - large packaging)

Indications for Use *(Describe)*
Luja Coude 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.

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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SPECIAL 510(K) SUMMARY

Submitted by:

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Date of Summary: October 25, 2023

Subject Device:

Trade or Proprietary Name:	Luja Coude (20108 Male CH18 - large packaging)
Item/Model Numbers:	20108
Common Name:	Urological catheter and accessories
Regulation/Classification Name:	Urological catheter and accessories
Regulation Number:	21 CFR 876.5130
Regulatory Class:	II
Product Code:	EZD
Review Panel:	Gastroenterology/Urology
Predicate Device:	K230165, Luja Coude The predicate device has not been subject of a design-related recall.
Reference Device:	K180258, SpeediCath Standard The reference device has not been subject of a design-related recall.

Device Description:

Luja Coude is a single-use, sterile catheter for intermittent urinary catheterization. The catheter has a flexible tip which 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 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 primary packaging provides the sterile barrier and contains a proof of seal for identification of opened products.

Luja Coude is available in one length (33cm) with a flexible tip and diameters of 8 Fr, 10 Fr, 12 Fr, 14 Fr, 16 Fr, and 18 Fr.

Luja Coudé CH/FR 18 differs from the predicate device in the catheter size variants. Luja Coudé (predicate) includes French size 8 (CH8) through French size 16 (CH16) variants compared to the subject device which is a line extension to the Luja Coudé. The reference device supports the inclusion of the 18 Fr size variant.

Indications for Use:

Luja Coude 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.

The subject and predicate devices have the same intended use.

Technological Characteristics Comparison

The table below summarizes the technological characteristics of Luja Coude 18Fr as compared to the predicate device.

Parameter	Subject device	Predicate device	Reference device
	Luja Coudé	**Luja** Coudé	**SpeediCath Standard (male models only)**
510(k) Number	Unassigned	K230165	K180258
Regulation Name	Urological catheter and accessories	Same	Same
Regulation Number	21 CFR 876.5130	Same	Same
Product Code	EZD	Same	GBM
Classification	II	Same	Same
Prescription Device	Yes	Same	Same

Intended Use	Intermittent catheterization through the urethra.	Same	Same
Indications for Use	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 for adult male patients only.	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 for adult male patients only.	Urinary catheter for intermittent use. The catheter is intended for use by patients with chronic 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.
Condition of Use	Intermittent use and single use	Same	Same
Drainage	Micro holes	Same	Eyelets
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	1years at submission (planned 2 years)	same	2 years
Available Sizes	Male, FR 18 / CH 18	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 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 Tiemann, FR 10 / CH 10 Tiemann, FR 12 / CH 12 Tiemann, FR 14 / CH 14 Tiemann, FR 16 / CH 16
Catheter Materials	Polyurethane	Same	Similar
Hydrophilic Coating	Hydrophilic Coating	Same	Same
Swelling media (Wetting Agent)	Saline solution with PEG	Same	Same
Tip Configuration	Flexible curved tip (bended)	Same	Straight (Nelaton) tip and Tiemann tip

Protective Sleeve Material	- Copoly (ethylene/octane) - Copoly (isobutylene/styrene)	Same	N/A
Inner Connector	Polyurethane White	Same	N/A no inner connector
Outer Connector material	Thermoplastic Polypropylene	Same	Thermoplastic polyurethane with masterbatches
Handle material	Thermoplastic Polypropylene	Same	
Primary Packaging Description	Single and double-loop pouch packages, dark grey	Single pouch package, dark grey	Similar (longer and thicker), green
Packaging Materials	Inner layer: PE-peel Outer layer: Printed PETP	Same	Oriented polyamide, aluminum, low-density polyethylene, ring-shaped opening feature
Effective Catheter Length	Effective length (according to ISO 20696:2018): 33cm (13 inches)	Same	Effective length (according to ISO 20696:2018): 35cm (13.9 inches)

Summary of Non-Clinical Performance Testing

The following test was submitted in this Special 510(k):

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.	

The following tests were leveraged from prior testing cleared under K230165. As applicable, the 18 fr size was included in analysis for all worst-case scenarios and included in testing. Test methods and protocols were reviewed and accepted as part of the review of K230165.

Non-clinical test summary:	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.
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: Test for in vitro cytotoxicity
	ISO 10993-10 :2021, Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization
	ISO 10993-11 :2017, Biological evaluation of medical devices, Part 11: Tests for systemic toxicity
	ISO 10993-18 :2020, Biological evaluation of medical devices, Part 18: Chemical characterization of medical device materials within a risk management process

	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
	ASTM D1894: 2014, Standard test method for static and kinetic coefficients of friction of plastic film and sheeting
	Coloplast Test Method TM 6058 Friction after 5 minutes
	Coloplast Test Method TM 6059 opening torque
	Coloplast Test Method TM 6100 sleeve collapse force
	Coloplast Test Method TM6129: Kink and Coude measurement
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.	
Packaging:	ISO 11607-1 :2019, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
	ASTM F2096 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
	EN 868-5 Packaging for terminally sterilized medical devices Sealable pouches and reels of porous materials and plastic film construction. Requirements and test methods
	ASTM F88/FM88 Standard Test Method for Seal Strength of Flexible Barrier Materials.
	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.	

No changes to the device materials, methods of manufacture, sterility process, and packaging were proposed in this submission compared to K230165. Therefore, leveraging these prior testing was found applicable.
The methods used in this Special 510(k) were the same methods used and accepted in K230165. Therefore, the use of well-established methods to evaluate the proposed change made this submission appropriate for a Special 510(k).

Conclusion
The performance and non-clinical testing demonstrate the subject device is as safe and effective as the predicate device.