July 17, 2026

Wellspect AB
Emad Ramzi
Sr. Regulatory Affairs Manager
Amniogatan 1, P.O.Box 14
Se-431 51 Sweden
Mölndal
SWEDEN

Re: K261658
Trade/Device Name: LoFric Origo Pro Coudé
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: June 24, 2026
Received: June 24, 2026

Dear Emad Ramzi:

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.	K261658

Please provide the device trade name(s).

LoFric Origo Pro Coudé

Please provide your Indications for Use below.

LoFric® Origo™ Pro Coudé is indicated for short- and long-term bladder management with intermittent urinary catheterization of adults and adolescents.

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 for LoFric Origo Pro Coudé

1. Submitter Information:

Wellspect AB
Aminogatan 1
P.O. Box 14
431 21 Mölndal

Contact Person: Emad Ramzi
Telephone Number: +46 31 376 32 41

Date Prepared: June 24, 2026

2. Device Name:

- Proprietary Name: LoFric® Origo™ Pro Coudé
- Common Name: Intermittent urinary catheter
- Classification Name: Urological catheter and accessories
- Classification Number: 21 CFR 876.5130
- Device Class: Class II
- Product Code: EZD, Catheter Straight

3. Predicate Device:

Type	Device Name	510(k)	Company Name
Predicate device	LoFric® Origo™	K250659	Wellspect AB

4. Description of Device:

The subject device: LoFric® Origo™ Pro Coudé is a range of sterile, single-use, urinary catheters designed as an intermittent pathway for drainage of the bladder. The catheters, designed to accommodate the individual anatomy of male users, are available in a single length (40 cm) with a flexible, pre-curved (Coudé), ball-shaped distal tip and diameters of 12Fr, 14Fr, and 16Fr. Each catheter features 12 drainage eyelets arranged in a vertical spiral configuration around the catheter tube, designed to promote efficient urine flow and reliable drainage performance. The catheters are individually packaged together with an extendable protective sleeve attached to the catheter along with a sterile water sachet (packet). The extendable protective sleeve is provided to minimize touching the catheter shaft directly during insertion and retraction. The water sachet is provided for wetting of the hydrophilic surface and is to be broken immediately before use in order to soak the tubing.

5. Indications for Use:
LoFric® Origo™ Pro Coudé is indicated for short- and long-term bladder management with intermittent urinary catheterization of adults and adolescents.

6. Comparison of Technological Characteristics:
The purpose of this Special 510(k) is to gain U.S. premarket clearance for the modification to the predicate device LoFric® Origo™ (K250659).

- The subject and predicate maintain the same indication for use.
- The subject and predicate maintain the same fundamental design, materials, hydrophilic coating, wetting fluid, packaging configuration, sterilization method, catheter dimensions, and user interface.

The key differences between the predicate device (K250659) and the subject device are: (1) an update to the catheter drainage eyelet configuration and (2) a modification to the distal tip design.

The predicate device includes two drainage eyelets and a straight, flexible, ball-shaped distal tip, whereas the proposed LoFric® Origo™ Pro Coudé incorporates twelve drainage eyelets arranged in a vertical spiral configuration around the catheter tube and a modified distal tip featuring a flexible, pre-curved (Coudé), ball-shaped distal tip.

An overview of the similarities and differences between the subject device and predicate devices are given in Table FS-1.
The predicate device (K250659) has not been subject to any design-related recalls.

7. Non-Clinical Performance Data
Based on the modifications made to the device in this Special 510(k), the following tests were impacted and repeated using the modified device. A summary of the following tests was submitted in this Special 510(k) to support the proposed change:

- *Catheter Flow rate*, verified by the test method in Annex E of ISO 20696:2018, *Sterile urethral catheters for single use.*
- *Catheter Strength,* verified by the test method in Annex A of ISO 20696, *Sterile urethral catheters for single use.*
- *Coating Appearance, verified in accordance with* ISO 20696, *Sterile urethral catheters for single use.*
- *Flexible, pre-curved Coudé tip Beam Bending stiffness*, verified by the internal method.
- *Flexible, pre-curved Coudé tip Insertion force*, verified by the internal method.

These test methods and protocols are identical to those used in the predicate submission (K250659) and were part of the information FDA evaluated during its review of that 510(k).

The testing below was leveraged from the predicate submission (K250659) and was not reviewed as part of this Special 510(k). For technological characteristics that are identical or similar to the predicate device, a risk assessment was conducted and determined that the testing and data obtained with the predicate device remain applicable and support substantial equivalence.

a) Qualification of biological safety assessment according to ISO 10993-1:2018, *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process* and FDA Guidance "Use of International Standard ISO 10993-1".

b) Test methods for confirmation of sterile barrier systems and packaging validation testing following requirements in:
- ISO 11607-1:2019, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- ISO 11607-2:2019, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.*
- ASTM D4169-22, *Standard Practice for Performance Testing of Shipping Containers and Systems.*
- ASTM D4332-14, *Standard Practice for Conditioning Containers Packages or Packaging Components for Testing.*
- ASTM F1929-15, *Standard test method for detecting seal leaks in porous medical packaging by dye penetration.*
- ASTM F88/F88M-23, *Standard Test Method for Seal Strength of Flexible Barrier Materials.*

c) Sterilization validation was performed according to
- ISO 11137-1:2006/(R)2015, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 11137-2:2013, *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

d) Shelf life and Performance bench testing was performed per applicable sections of ISO 20696:2018, *Sterile urethral catheters for single use*, and internal test methods to document the following properties of the catheters:
- *Connector security* was verified by the test method in Annex B of ISO 20696:2018.
- *Kink stability* was verified by the test method in Annex G of ISO 20696:2018.
- *Friction* was verified by internal test method.
- *Peak tensile force* was verified by the test method in Annex H of ISO 20696:2018.
- *Water retention* was verified by internal test method.
- *Catheter Sleeve insertion aid strength* was verified by internal test method.
- *Packaging sterile integrity* was verified by internal test method.
- *Primary package seal strength* was verified by internal test method.

8. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the subject LoFric® Origo™ Pro Coudé.

9. Conclusion

Based on the comparison of technological characteristics and the results of the non-clinical performance testing, the subject device is substantially equivalent to the predicate device (K250659). The only modifications, an increased number of drainage eyelets and a modified distal tip, were evaluated through non-clinical bench testing, which confirmed that the changes do not adversely affect device safety or effectiveness. All other design features, materials, intended use, and performance characteristics remain unchanged from the predicate device. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. Therefore, the LoFric® Origo™ Pro Coudé is as safe and effective as the predicate device and performs as intended when used for intermittent urinary catheterization

Table FS-1: Comparison of technological characteristics between subject and predicate devices

Element	Subject Device LoFric® Origo™ Pro Coudé	Predicate Device LoFric® Origo™	Differences between proposed device and predicate device
Indication for Use	LoFric® Origo™ Pro Coudé is indicated for short- and long-term bladder management with intermittent urinary catheterization of adults and adolescents.	LoFric® Origo™ For short- and long-term bladder management with intermittent urinary catheterization.	None
Product Code	EZD	EZD	None
Device for Prescription use	Yes	Yes	None
Anatomical site	Bladder through the Urethra	Bladder through the Urethra	None
Catheter tip Configuration	Flexible (pre-curved, ball-shaped Coudé) tip	Nelaton (Straight) tip, Tiemann (Coudé) tip & Flexible (Straight ball-shaped) tip	Both devices include straight and coudé tip concepts; the proposed device uses a flexible pre-curved coudé ball-tip variant.
Type/Sizes	Flexible Coudé tip *with protective Sleeve* CH.12, 14 & 16 in 40cm length	Flexible Straight tip *with protective Sleeve* CH.12, 14 & 16 in 40cm length Nelaton tip *with insertion grip* CH.8, 10 & 12 in 30cm length Nelaton tip *with insertion grip* CH.10, 12, 14, 16 & 18 in 40cm length	The proposed device includes a subset of sizes (CH12–16, 40 cm) with a flexible coudé tip and protective sleeve, within the broader range of predicate sizes, lengths, and configurations.

Element	**Subject Device** **LoFric® Origo™ Pro Coudé**	**Predicate Device** **LoFric® Origo™**	**Differences between proposed device and predicate device**
		Flexible tip *with insertion grip* CH.12, 14 & 16 in 40cm length Tiemann tip *with insertion grip* CH.10, 12, 14, 16 & 18 in 40cm length Nelaton tip *with protective Sleeve* CH.12, 14 & 16 in 40cm length	
Number and size of Drainage Eyelets	12 Approx. 1.45 × 0.45 mm [L × W]	2 Approx. 3.6×1.3 mm or 4.3×1.6 mm [L × W], depending on CH size	The proposed device incorporates twelve drainage eyelets arranged in a vertical spiral configuration around the catheter tube, with a harmonized eyelet size across all CH sizes.
Catheter tube Material	Polyolefin based elastomer (POBE)	Polyolefin based elastomer (POBE)	None
Hydrophilic surface coating	Polyvinylpyrrolidone (PVP)	Polyvinylpyrrolidone (PVP)	None
Hydrophilic coating activation (wetting fluid)	Integrated water sachet with sterile water & NaCl	Integrated water sachet with sterile water& NaCl	None
Connector	Color coded end-funnel	Color coded end-funnel	None
Packaging	Multilayer coextruded film with polymer-based top and bottom foils and resealable label	Multilayer coextruded film with polymer-based top and bottom foils and resealable label	None

Element	**Subject Device** **LoFric® Origo™ Pro Coudé**	**Predicate Device** **LoFric® Origo™**	**Differences between proposed device and predicate device**
Sterilization method	e-beam	e-beam	None
Sterility assurance level	10^{-6}	10^{-6}	None
Condition of Use	Single Use	Single Use	None
Shelf Life	2 years	2 years	None