



April 24, 2026

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

Re: K260999  
Trade/Device Name: LoFric Elle Pro  
Regulation Number: 21 CFR 876.5130  
Regulation Name: Urological Catheter and accessories  
Regulatory Class: II  
Product Code: EZD  
Received: March 26, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Negeen Haghighi -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.

K260999

?

Please provide the device trade name(s).

?

LoFric Elle Pro

Please provide your Indications for Use below.

?

LoFric Elle Pro is intended for intermittent urinary catheterization

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](#))

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## Special 510(k) SUMMARY for LoFric Elle Pro

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: April 24, 2026

2. Device Name:

- Proprietary Name: LoFric Elle Pro
- 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 <sup>®</sup> Elle <sup>™</sup>	K211212	Wellspect HealthCare, a Dentsply Sirona company at the time of clearance

4. Description of Device:

The subject device: LoFric<sup>®</sup> Elle<sup>™</sup> Pro, is a range of sterile, single-use, urinary catheters designed as an intermittent pathway for drainage of the bladder. The catheter is pre-lubricated with a hydrophilic coating and immersed in water-based wetting fluid within its primary package. The primary package contains a sealed water container from which the wetting fluid migrates to the catheter tubing and activates the catheter surface. This results in minimal steps for preparation prior to use. LoFric<sup>®</sup> Elle<sup>™</sup> Pro is available in a single length (10 cm) with a Nelaton (straight) tip and diameters of 10Fr, 12Fr, and 14Fr, to accommodate the individual anatomy of female users. The 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.

5. Indications for Use:

LoFric<sup>®</sup> Elle<sup>™</sup> Pro is indicated for intermittent urinary catheterization.

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<sup>®</sup> Elle<sup>™</sup> (K211212).

- 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 (K211212) and the subject device is:

- The Number of drainage eyelets. The predicate device includes two drainage eyelets, whereas the LoFric<sup>®</sup> Elle<sup>™</sup> Pro incorporates twelve drainage eyelets arranged in a vertical spiral configuration around the catheter tube, with a harmonized eyelet size across all CH sizes.

An overview of the similarities and differences between the subject device and predicate devices are given in Table FS-1.

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 were 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*.
- *Catheter Beam Bending stiffness*, verified by the internal method.
- *Friction and coating appearance*, verified by the internal method.

These test methods and protocols are identical to those used in the predicate submission (K211212) and were part of the information FDA evaluated during its review of that 510(k).

The testing below was leveraged from the predicate submission (K211212) and were not reviewed as part of this special 510(k):

- 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, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- ISO 11607-2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.*
- ASTM D4169-16, *Standard Practice for Performance Testing of Shipping Containers and Systems.*
- ASTM D4332-14, *Standard Practice for Conditioning Containers Packages or Packaging Components for Testing.*

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:

- *Peak tensile force* was verified by the test method in Annex H of ISO 20696.
- *Kink stability* was verified according to ISO 20696.
- *Diameter sizes* were verified by design according to ISO 20696.
- *Water retention* was verified by the internal method.
- *Osmolality* was verified by the internal method.
- *Packaging sterile integrity* was verified by the internal method.
- *Flexural Strength* was verified by the internal method.
- *pH level* was verified by the internal method.

#### 8. Clinical Performance Data

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

#### 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 (K211212). The only modification, an increased number of drainage eyelets, was evaluated through nonclinical bench testing, which confirmed that the change does not adversely affect device safety and effectiveness. All other design features, materials, intended use, and performance characteristics remain unchanged from the predicate. Therefore, the LoFric® Elle™ Pro 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**

<b>Element</b>	<b><u>Subject Device</u> LoFric® Elle™ Pro</b>	<b><u>Predicate Device</u> LoFric® Elle™</b>	<b>Differences between proposed device and predicate device</b>
Indication for Use	For intermittent urinary catheterization	For 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
Type/Sizes	Nelaton CH.10, 12 & 14	Nelaton CH.10, 12 & 14	None
Number of Drainage Eyelets	12	2	Proposed device incorporates twelve drainage eyelets arranged in a vertical spiral configuration around the catheter tube.
Tip Configuration	Straight (Nelaton) tip	Straight (Nelaton) tip	None
Catheter Material	Polyolefin based elastomer (POBE)	Polyolefin based elastomer (POBE)	None
Hydrophilic surface coating	Polyvinylpyrrolidone (PVP)	Polyvinylpyrrolidone (PVP)	None
Manufacturing method	Dip-coating technology with Ethanol coating solvent	Dip-coating technology with Ethanol coating solvent	None
Features	Single Use, pre-wet and ready to use	Single Use, pre-wet and ready to use	None
Wetting fluid	Sterile water with glycerol solution	Sterile water with glycerol solution	None
Connector	Color coded end-funnel	Color coded end-funnel	None

<b>Element</b>	<b><u>Subject Device</u> LoFric® Elle™ Pro</b>	<b><u>Predicate Device</u> LoFric® Elle™</b>	<b>Differences between proposed device and predicate device</b>
Packaging	A sealed lower and upper container made by Polypropylene (PP)	A sealed lower and upper container made by Polypropylene (PP)	None
Sterilization method	e-beam	e-beam	None
Sterility assurance level	10 <sup>-6</sup>	10 <sup>-6</sup>	None
Condition of Use	Single Use	Single Use	None