September 26, 2025

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

Re: K250659
Trade/Device Name: LoFric Origo
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: March 5, 2025
Received: August 28, 2025

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: 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 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.

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,

Jessica K. Nguyen -S

Jessica K. Nguyen
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

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.*

Submission Number *(if known)*

K250659

Device Name

LoFric Origo

Indications for Use *(Describe)*

LoFric Origo is indicated for short- and long-term bladder management with intermittent urinary catheterization.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) SUMMARY for LoFric Origo™

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: September 26, 2025

2. Device Name:

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

3. Predicate and Reference Devices:

| Type | Device Name | 510(k) | Company Name |
|---|---|---|---|
| Predicate device | LoFric® Primo™ | K122078 | Wellspect HealthCare (formerly Astra Tech AB) |

4. Description of Device:

The subject device: LoFric® Origo™ 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 various lengths and French sizes, and come in three tip designs: Nelaton (straight tip), Flexible (straight ball-shaped tip), and Tiemann (Coudé tip). Each catheter is individually packaged together with an adjustable insertion grip, or an extendable protective sleeve attached to the catheter along with a sterile water sachet (packet). The adjustable insertion grip or the extendable protective sleeve are 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™ is indicated for short- and long-term bladder management with intermittent urinary catheterization.

6. Intended use population:
LoFric® Origo™ catheters are intended for male, and pediatric patients (adolescents and children).

7. Comparison of Technological Characteristics:
The purpose of this Traditional 510(k) is to gain U.S. premarket clearance for the modification to the predicate device LoFric® Primo™ (K122078).

- The subject and predicate devices have the same intended use for intermittent urinary catheterization.
- The subject and predicate devices are sterile, single use, hydrophilic coated catheters, use the same operational principle and incorporating the same tubing and coating material.
- The subject and predicate devices have similar packaging configurations, each including a separate water sachet for activation, and are sterilized using the same sterilization method (e-beam).

The key differences between the predicate device (K122078) and the subject device are:

- Minor adjustment to the device's indication for use phrase, without affecting the substance or meaning of the indication previously cleared under (K122078).
- Replacing the previously cleared optional insertion aid with an adjustable insertion grip or an extendable protective sleeve, assembled on the catheter body to facilitate a non-touch technique.
- Introduction of a 30 cm Nelaton tip catheter in French sizes: CH.8, 10 and 12.
- Introduction of a 40 cm Flexible, straight ball-shaped tip catheter in French sizes: CH 12, 14 and 16.
- Modification in the single package material and design.
- Enhancing the previously cleared funnel material to a medical-grade version, incorporating FDA-listed color additives.
- Use of a different dip-coating solvent.
- Updates made to Instructions for Use to include pictorial instructions, include device warnings/precautions and adverse reaction information for patient awareness.

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

8. Non-Clinical Performance Data
Non-clinical testing data that was submitted, referenced, or relied upon to demonstrate substantial equivalence includes:

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". Testing performed included Chemical characterization, Cytotoxicity, Irritation, Sensitization, Genotoxicity, and Pyrogenicity.

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:
- *Flow rate* was verified by the test method in Annex E of ISO 20696:2018.
- *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.
- *Coating quality* was verified by internal test method.
- *Catheter strength* was verified by the test method in Annex A of ISO 20696:2018.
- *Peak tensile force* was verified by the test method in Annex H of ISO 20696:2018.
- *Water retention* was verified by internal test method.
- *Flexible tip bending stiffness* was verified by internal test method.
- *Flexible tip insertion force* 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.

All tests met the pre-determined acceptance criteria.

The results of the testing show substantial equivalence in performance of the subject device when compared to the predicate device (K122078).

9. Clinical Performance Data

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

10. Conclusion

The subject device and the predicate device (K122078) share the same intended use and have similar indications for use. Both are sterile, single-use catheters that incorporate the same basic design, use the same or similar materials, and have a similar packaging configuration, i.e., a urinary catheter with a sterile water sachet for activation.

Performance data have been included to address the safety and effectiveness of the subject devices. The results of non-clinical bench testing, combined with the design, biocompatibility, and intended use comparison to the predicate device (K122078), demonstrate that the subject devices are as safe, as effective, and perform as well as the legally marketed device.

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

| Element | Subject Device | Predicate Device | Discussion |
|---|---|---|---|
| | **LoFric® Origo™** | **LoFric® Primo™ (K122078)** | |
| **Product Code** | EZD | EZD | Same |
| **Device for Prescription use** | Yes | Yes | Same |
| **Indications for Use** | LoFric Origo is indicated for short- and long-term bladder management with intermittent urinary catheterization. | LoFric Primo is indicated for intermittent urinary catheterization. | Both the subject and predicate devices are used for intermittent urinary catheterization. The additional phrase "short- and long-term bladder management" in the subject device indication clarifies that the device is suitable for patients who use intermittent catheterization for both short and long periods. However, it does not imply that the catheter itself is meant for long-term indwelling use. |
| **Anatomical site** | Bladder through the Urethra | Bladder through the Urethra | Same |
| **Patient population** | Intended for male, and pediatric patients. | Intended for male, female and pediatric patients. | The patient population for the subject device excludes the female population. |
| **Principal of operation** | • Squeeze water pocket<br>• Peel pack open<br>• Insert catheter<br>• Empty bladder<br>• Withdraw catheter<br>• Dispose device | • Squeeze water pocket<br>• Peel pack open<br>• Insert catheter<br>• Empty bladder<br>• Withdraw catheter<br>• Dispose device | Same |
| **Catheter tip Configuration** | Nelaton (Straight) tip,<br>Tiemann (Coudé) tip &<br>Flexible (Straight ball-shaped) tip | Nelaton (Straight) tip &<br>Tiemann (Coudé) tip | The subject device includes an additional tip configuration, i.e., a Flexible (straight ball-shaped) tip. |

| Element | Subject Device<br>LoFric® Origo™ | Predicate Device<br>LoFric® Primo™ (K122078) | Discussion |
|---|---|---|---|
| | | | The Flexible tip insertion force and bending stiffness was evaluated to support substantial equivalence. |
| **Type/Sizes** | Nelaton *with insertion grip*<br>CH.8, 10 & 12<br>in 30cm length<br><br>Nelaton *with insertion grip*<br>CH.10, 12, 14, 16 & 18<br>in 40cm length<br><br>Flexible *with insertion grip*<br>CH.12, 14 & 16<br>in 40cm length<br><br>Tiemann *with insertion grip*<br>CH.10, 12, 14, 16 & 18<br>in 40cm length<br><br>Nelaton *with protective Sleeve*<br>CH.12, 14 & 16<br>in 40cm length<br><br>Flexible *with protective Sleeve*<br>CH.12, 14 & 16<br>in 40cm length | Nelaton<br>CH.8, 10, 12, & 14<br>in 15cm length<br><br>Nelaton<br>CH.6, 8, 10, 12, 14, 16, & 14<br>in 20cm length<br><br>Nelaton<br>CH.8, 10, 12, 14, 16, & 18<br>in 40cm length<br><br>Tiemann<br>CH.10, 12, 14, 16 &18<br>in 40cm length | The subject LoFric Origo catheters are available in 30 cm and 40 cm lengths.<br><br>The 30 cm catheter has been introduced to the LoFric Origo line to enhance handling for male users.<br><br>Both the 30 cm and 40 cm catheters, available in French sizes CH8 to CH18, come with an insertion grip to facilitate the non-touch technique.<br><br>The protective sleeve is included only with the 40 cm catheters in French sizes CH12, CH14, and CH16. |
| **Catheter tube Material** | Polyolefin based elastomer (POBE) | Polyolefin based elastomer (POBE) | Same |
| **Hydrophilic surface coating** | Polyvinylpyrrolidone (PVP) & NaCl | Polyvinylpyrrolidone (PVP) & NaCl | Same |
| **Hydrophilic coating activation** | Integrated water sachet with sterile water & NaCL | Integrated water sachet with sterile water & NaCL | Same |
| **Catheter funnel** | Color coded end-funnel | Color coded end-funnel | Same base material (TPS), different material grade as predicate device. |

| Element | Subject Device<br>LoFric® Origo™ | Predicate Device<br>LoFric® Primo™ (K122078) | Discussion |
|---|---|---|---|
| | | | Biocompatibility testing was performed to address material formulation differences between the subject and predicate device in support of substantial equivalence. |
| **Catheter insertion guide** | Adjustable Insertion Grip<br>or<br>an Extendable Protective Sleeve for no-touch functionality. | Optional Insertion Aid, for no-touch functionality. | The subject device insertion grip or protective sleeve both have the same functionality as the predicate device insertion aid to prevents direct contact with the catheter shaft during use. |
| **Single Package** | Multilayer cast coextruded film with: a polyolefin/polyethylene bottom foil, a polyester/ polyethylene top foil and a polyester resealable label | Three-layer co-extruded polyethylene (PE) film | Different packaging materials and designs have been used. Packaging testing has been conducted and included to address material formulation and sterility integrity, supporting substantial equivalence. |
| **Resealable label** | Yes | No | The subject device features a resealable label for accessing the catheter. |
| **Sterilization method** | E-beam | E-beam | Same |
| **Condition of Use** | Single Use | Single Use | Same |
| **Shelf Life** | 2 years | 2 years | Same |