February 17, 2022

Dentsply Sirona
Rebecca Sporer
Regulatory Affairs Specialist
221 West Philadelphia Street, Suite 60W
York, PA 17401

Re: K211212
Trade/Device Name: LoFric® Elle™
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: January 18, 2022
Received: January 19, 2022

Dear Rebecca Sporer:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211212

Device Name
LoFric® Elle™

Indications for Use *(Describe)*
For 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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Dentsply Sirona
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510(k) SUMMARY
LoFric® Elle™
K211212

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17404

Contact Person: Rebecca Sporer
Telephone Number: 717-849-4793
Fax Number: 717-849-4343
Email: Corporate-RA@dentsplysirona.com
Date Prepared: February 15, 2022

2. Device Name:
   - Proprietary Name: LoFric® Elle™
   - Classification Name: Urological catheter and accessories
   - Classification Number: 876.5130
   - Device Class: II
   - Product Code: EZD

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
LoFric® Sense™	K123751	Wellspect HealthCare (a division of Dentsply IH AB)

4. Description of Device:

The proposed device: LoFric® Elle™, 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® Elle™, is available in one length (10cm) with a Nelaton (straight) tip and diameters of 10 Fr, 12 Fr and 14 Fr, to accommodate individual anatomy of female users.

5. Indications for Use:

For intermittent urinary catheterization

6. Substantial Equivalence:

Technological Characteristics

The subjects of this Traditional 510(k) is the introduction of the LoFric® Elle™, which is submitted due to the following principles:

- The subject and predicate device are sterile, single use, hydrophilic coated catheters intended for intermittent urinary catheterization.

- The subject device shares the same coating and is made of the same basic tubing material as the predicate device.

The difference between LoFric® Elle™, and the predicate device is the different:

- Wetting fluid and agent.
- Packaging configuration and visual appearance.
- Slightly modified chemical composition of the tubing base material.
- Different dip-coating solvent.

These modifications are made for ease of use and discretion improvements.
An overview of the similarities and differences between the subject and predicate device is given in Table 1.

7. Non-Clinical Performance Data.

Non-clinical testing data that was submitted, referenced, or relied upon to demonstrate substantial equivalence included:

a) Biocompatibility testing was performed 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) Bench testing was performed according to ISO 20696:2018 (Sterile urethral catheters for single use) and internal test methods.

Performance testing was conducted according to applicable sections of standards in order to document the following properties of the LoFric Elle hydrophilic catheter:

- Strength was verified by the test method in Annex A of ISO 20696.
- Flow rate was verified by the test method in Annex E of ISO 20696.
- Peak tensile force was verified by the test method in Annex H of ISO 20696.
- Kink stability was verified according to ISO 20696.
- Coating appearance was verified according to ISO 20696.
- Diameter sizes were verified by design according to ISO 20696.
- Water retention was verified by the internal method.
- Coefficient of friction 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.
- Beam Bending stiffness was verified by the internal method.
- pH level was verified by the internal method.

All tests passed.

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

d) Requirements for materials, sterile barrier systems, and packaging systems was conducted according to ISO 11607-1:2006/(R)2010 *(Packaging for terminally sterilized medical devices - Part 1).*

e) Validation requirements for forming, sealing, and assembly processes was conducted according to ISO 11607-2:2006/(R)2010 *(Packaging for terminally sterilized medical devices - Part 2).*

f) Environmental conditioning and simulated shipping distribution were conducted according to
- ASTM D4332-14, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing and;
- ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems.

g) Real time and accelerated aging shelf life testing was completed according to ASTM F1980-16 *(Standard guide for accelerated aging of sterile barrier systems for medical devices)*.

All tests met the pre-determined acceptance criteria.

8. Clinical Performance Data.

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

9. Conclusion Regarding Substantial Equivalence

The subject device and the predicate device have the same intended use for intermittent urinary catheterization. All are single use catheters coated with polyvinyl pyrrolidone and available in one length with different diameters for female users. Performance data are included to address the safety of the subject device. The results of non-clinical bench testing, combined with the design, biocompatibility, and intended use comparison to the predicate device support the substantial equivalence of the subject device.

Table 1. Similarities and Differences between the subject and predicate device

Element	**Proposed Device** **LoFric® Elle™**	**Predicate Device** **LoFric® Sense™ (K123751)**	**Differences between proposed device and predicate device**
Indications for Use	LoFric Elle is intended for intermittent urinary catheterization	LoFric Sense is intended 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. 8, 10, 12 & 14	The proposed device is not available in CH.8/ FR.8 diameter.
Effective length *Acco.to: ISO 20696*	10 cm (4 inches)	10 cm (4 inches)	None
Tip Configuration	Nelaton (Straight) tip	Nelaton (Straight) tip	None
Catheter Material	Polyolefin based elastomer (POBE)	Polyolefin based elastomer (POBE)	The proposed device is composed of identical base material with slightly different chemical composition. Biocompatibility and performance testing has been conducted and included to address detailed material formulation differences between the subject and predicate devices in support of substantial equivalence.
Hydrophilic surface coating	Polyvinylpyrrolidone (PVP)	Polyvinylpyrrolidone (PVP)	None
Features	Single Use, pre-wet and ready to use	Single Use with Integrated water packet	The proposed device is ready to use, immersed in wetting fluid without separate water packet.
Wetting fluid	Sterile water with glycerol solution	Sterile water with salt solution	The proposed device uses glycerol as wetting agent. Performance and biocompatibility testing has been conducted and included to

Element	Proposed Device LoFric® Elle™	Predicate Device LoFric® Sense™ (K123751)	Differences between proposed device and predicate device
			address the differences between the subject and predicate devices in support of substantial equivalence.
Connector	Color coded end-funnel	Color coded end-funnel with sleeve for non-touch technique during insertion	The proposed device has a 12 cm lower container which can be re-connected as a L-shape handle for non-touch technique during insertion.
Packaging	A sealed lower and upper container made by Polypropylene (PP)	Laminate foil of polyester with aluminum oxide (PET/Alox), linear low-density polyethylene (LLDPE) Water packet: aluminum foil	The proposed device has different packaging configuration and visual appearance for ease of use (ready to use)
Sterilization method	e-beam	e-beam	None
Condition of Use	Single Use	Single Use	None