



September 23, 2026

Teleflex Medical
Aisling Foley
Senior Manager Regulatory Affairs
Ida Business & Technology Park
Garrycastle, Dublin Rd.
Athlone, Co. Westmeath
IRELAND

Re: K261418
Trade/Device Name: Liquick X-treme, Liquick X-treme Plus
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: August 25, 2026
Received: August 25, 2026

Dear Aisling Foley:

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.

K261418

?

Please provide the device trade name(s).

?

Liquick X-treme, Liquick X-treme Plus

Please provide your Indications for Use below.

?

These catheters are indicated for the routine drainage of urine from the bladder. These catheters are not intended or designed for indwelling use.

Catheters are indicated for use in male and female adults and pediatric patients in the following pediatric subgroups:

Children (2 years old to less than 12 years old),

Adolescents (12 years old to less than 18 years old), and

Transitional Adolescents (18 years old to less than 22 years old but treated like adult).

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)

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510(k) Summary

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A. Name, Address, Phone and Fax Number of Applicant

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IDA Business and Technology Park, Dublin Road,
Athlone
Co Westmeath
Ireland
Phone: +353 (0) 9 06 46 08 00
Fax: +353 (0) 14 37 07 73

B. Contact Person

Aisling Foley
Sr. Manager Regulatory Affairs – Product Management

C. Date Prepared

September 23, 2026

D. Device Name

Trade Name:	Liquick X-treme
Common Name:	Urological Catheter and Accessories
Product Code:	EZD
Regulation Number:	CFR 876.5130
Classification:	II
Classification Panel:	Gastroenterology/Urology

E. Predicate Device

This submission demonstrates substantial equivalence to the predicate device, Rusch Floccath Quick Hydrophilic Intermittent catheters, K183461. The predicate device has not been subject to a design-related recall.

510(k) Summary

F. Device Description

Liquick X-treme consists of a pre-activated hydrophilic-coated intermittent catheter, covered by a protective sleeve. Liquick X-treme Plus is identical to Liquick X-treme, with the addition of a pre-connected urine bag. Device dimensions range from French gauge (Fr.) / Charrière (Ch) Ch06 to Ch16 in outer diameter (OD). The catheter is available in lengths of 20 cm, 30 cm and 43 cm, with an Ergothan, Nelaton or Tiemann tip. Liquick X-treme is manufactured of PVC, provided sterile, single use, and disposable, with proximal funnel and protective sleeve and introduction aid.

G. Indications for Use

These catheters are indicated for the routine drainage of urine from the bladder. These catheters are not intended or designed for indwelling use.

Catheters are indicated for use in male and female adults and pediatric patients in the following pediatric subgroups:

Children (2 years old to less than 12 years old),
Adolescents (12 years old to less than 18 years old), and
Transitional Adolescents (18 years old to less than 22 years old but treated like adult).

H. Substantial Equivalence

The subject device is substantially equivalent to the predicate device with respect to intended use, technology and construction. The difference between the predicate and the subject device is minor and any risks have been mitigated through testing. **Table 1** summarizes the similarities and differences between the subject and predicate device.

510(k) Summary

1: Comparison of Predicate Device vs. Subject Device

Features	Teleflex Medical Rusch FloCath Quick Urological Catheter (Predicate Device)	Liquick X-treme & Liquick X-treme Plus (Subject device)	Similarities and differences
Classification Name	Catheter, Urethral	Urological Catheter and Accessories	Classification name amended by FDA for new marketing applications
Regulation Number	876.5130	Same	Same
FDA Procode	GBM	EZD	GBM code obsoleted by FDA for new marketing applications
Class	II	Same	Same
Indication for Use	The Rusch Intermittent catheter is a tubular device that is inserted through the urethra and is used to pass urine from the bladder	These catheters are indicated for the routine drainage of urine from the bladder. These catheters are not intended or designed for indwelling use. Catheters are indicated for use in male and female adults and pediatric patients in the following pediatric subgroups: Children (2 years old to less than 12 years old), Adolescents (12 years old to less than 18 years old), and Transitional Adolescents (18 years old to less than 22 years old but treated like adult).	Equivalent, with inclusion of target population.
Single Use	Yes	Yes	Same
Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female	Same
Size Range	6-20 Fr.	6-16 Fr.	The subject devices are within the size range cleared in the predicate
Overall Length	40 cm	20-43cm	The length of catheter is selected based on patient anatomy. The difference in length does not introduce new risks.
Shaft	Tubular	Tubular	Same

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Features	Teleflex Medical Rusch FloCath Quick Urological Catheter (Predicate Device)	Liquick X-treme & Liquick X-treme Plus (Subject device)	Similarities and differences
Shaft Material	PVC	PVC	Same
Coating	Hydrophilic	Hydrophilic	Same
Biocompatibi lity	Complies with ISO 10993-1	Complies with ISO 10993-1	Same
Tip	Nelaton, Olive, or Tiemann tip	Nelaton, Ergothan or Tiemann tip	Equivalent
Eyelets	Yes	Yes	Same
Liquid for Wetting	0.9% Sterile saline solution	0.9% Sterile saline solution	Same
Primary Packaging	Paper and film peel back	Aluminium foil pouch	Material difference does not introduce new risks
Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide	Gamma Irradiation	Meets requirements. Same SAL 10 ⁻⁶
Shelf-life	5 Years	2 Years	Shelf life within the shelf life of the predicate device.

I. Comparison to the Predicate

Table 1 illustrates the similarities and differences between the subject device, Liquick X-treme, and the predicate device. The basic technological and operating principles are the same for the devices.

Both the subject device and predicate device are intended for the same patient populations, adult and pediatric, male and female. Both the subject device and predicate device are disposable, single use devices. As evidenced by comparison Table 1, there are no significant differences that would affect safety and efficacy.

J. Summary of Non-Clinical Testing

- Biocompatibility was conducted per ISO 10993-1– Biological Evaluation of Medical Devices -Part 1: Evaluation and testing within a risk management process:
 - Cytotoxicity
 - Sensitization
 - Irritation
 - Acute Systemic Toxicity
 - Subacute Systemic Toxicity
 - Material Mediated Pyrogenicity
- Sterilization validation was conducted per the following FDA-recognized standards:
 - ISO 11137-1 – Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
 - ISO 11137-2 – Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose.
- Transportation simulation, package integrity and shelf-life testing was conducted following the requirements of:
 - 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 F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
 - 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.
 - ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

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- Non-clinical Performance and shelf life testing was conducted per ISO 20696:2018, *Sterile urethral catheters for single use* and ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*.
 - 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.
 - Peak tensile force was verified by the test method in Annex H of ISO 20696:2018.
 - Flow rate was verified by the test method in Annex E of ISO 20696:2018.
 - Friction was verified by internal test method.

K. Conclusion

The **Liquick X-treme** devices have the same intended use and technological characteristics as the predicate. Test results demonstrate that the subject devices meet their intended use and perform as well as the legally marketed predicate device. Any differences in technological characteristics do not raise different questions of safety and effectiveness. The subject devices are substantially equivalent to the predicate device.