July 3, 2025

Shenzhen Trious Medical Technology Co., Ltd
% Kang Kyra
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan District
Shanghai
CHINA

Re: K250448
Trade/Device Name: Disposable Percutaneous Nephrostomy Dilatators
Regulation Number: 21 CFR 21 CFR 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: Class II
Product Code: EZN
Received: May 28, 2025

Dear Kang Kyra:

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, 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, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
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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.

510(k) Number *(if known)*
K250448

Device Name
Disposable Percutaneous Nephrostomy Dilators

Indications for Use *(Describe)*
Disposable Percutaneous Nephrostomy Dilators:
Dilator for tract preparation and splittable working sheath to protect the parenchyma.

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

I. Submitter

Shenzhen Trious Medical Technology Co., Ltd
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Preparation date: July 2, 2025

Submission Correspondent
Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Subject Device

Device Trade Name:	Disposable Percutaneous Nephrostomy Dilators
Classification Name:	Ureteral dilator
Regulation Number:	21 CFR 876.5470
Regulatory Class:	Class II
Product code:	EZN
Review Panel:	Gastroenterology/Urology

III. Predicate Devices

510(k) Number:	K170531
Trade name:	Ureteral Dilators and Percutaneous Nephrostomy Dilators
Common name:	Ureteral Dilators and Percutaneous Nephrostomy Dilators
Classification:	Class II
Product Code:	EZN
Manufacturer	Coloplast Corporation

The predicate device has not been subject of a design related recall

Device description
Disposable Percutaneous Nephrostomy Dilators：

The Disposable Percutaneous Nephrostomy Dilators consists of dilator tube and tearing sheath. The body of the tearing sheath is made of polytetrafluoroethylene (PTFE), the tearing handle is made of acrylonitrile-butadiene-styrene copolymer (ABS).
The body of the dilator tube is made of polypropylene (PP), the connector of the dilator tube is made of polypropylene (PP).

The Disposable Percutaneous Nephrostomy Dilators are sterile single use device. EO sterilization, shelf life of 3 years.

These devices must be used in operating theatre, under aseptic environment.
Duration of use for the different components:

Components	Duration of use
Tearing sheath tube	＜24h
Dilator tube	＜24h

Intended population: adult patients.

IV. Indications for use

Disposable Percutaneous Nephrostomy Dilators：

Dilator for tract preparation or splittable working sheath to protect the parenchyma.

V. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in below table

Table 5.1 General Comparison of Disposable Percutaneous Nephrostomy Dilators

Characteristics	**Subject device**	**Predicate device K170531**	**Discussion**
Devices name	Disposable Percutaneous Nephrostomy Dilators	Percutaneous Nephrostomy Dilators	n/a
Product code	EZN	EZN	Same
Indication For Use	Dilator for tract preparation and splittable working sheath to protect the parenchyma.	Dilator for tract preparation or splittable working sheath to protect the parenchyma.	Same
Appearance/structure	The Disposable Percutaneous Nephrostomy Dilators consists of dilator tube and tearing sheath tube.	simple dilators and a splittable working sheath	Same

Dilator tube size	8,10,12, 14, 16, 18, 20, 22, 24Fr	6, 8, 10, 11, 12, 14Fr	Difference 1
Length	195±10(mm)	About 21cm	Difference 2
Material	The body of the tearing sheath is made of polytetrafluoroethylene (PTFE), the tearing handle is made of acrylonitrile-butadiene-styrene copolymer (ABS). The body of the dilator tube is made of polypropylene (PP), the connector of the dilator tube is made of polypropylene (PP).	The simple dilators are hollow tubes made in Polyether Block Amide (PEBA) The dilator with splittable sheath consists of a high-density polyethylene (HDPE) dilator fitted with a Polytetrafluoroethylene (PTFE) sheath.	Difference 3
Sterile	Yes	Yes	Same

Difference 1
The diameters of the subject device are representative of similar, legally marketed devices. The difference does not raise different questions of safety or effectiveness.

Difference 2
The lengths of the subject device are representative of similar, legally marketed devices. The difference does not raise different questions of safety or effectiveness.

Difference 3
Biocompatibility evaluation of the Disposable Percutaneous Nephrostomy Dilator was evaluated has been carried out in accordance with the FDA guidance "Use of International Standard ISO 10993-1." This does not raise new questions of safety and effectiveness.

VI. Non-clinical Performance testing

The following performance testing was conducted on the device to support the determination of substantial equivalence.

- Dimensional Testing
- ISO 11070:2014 Sterile single-use intravascular introducers, dilators and guidewires

- Resistance to Flattening

Biocompatibility testing

Biocompatibility of the subject device was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1" The following testing was conducted:

- Cytotoxicity-ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- Sensitization-ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- Irritation-ISO 10993-23 Biological evaluation of medical devices - Part 23: Tests for irritation
- Acute Systemic-ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Sterility and Shelf -life

- ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ISO11737-2:2019 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- ASTM F1980-2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D3078-02-2021 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- FDA guidance document, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile"
- ASTM F1886-16 Standard Test Method for Determining Integrity of Seals for Flexible

Packaging by Visual Inspection

VII.Conclusion

The conclusions drawn from the performance testing demonstrate that the subject devices are as safe and as effective as the legally marketed predicate device (K170531). Accordingly, the subject devices are substantially equivalent to the predicate device.