June 18, 2024

Yuwonmeditech Co., Ltd.
Bae Ji Hyeon
Manager, Regulatory Affairs
Rm 103, 104, 108, 113, 114, 117, Donghwa Medical Instrument
147-1, Donghwagongdan-ro, Munmak-eup
Wonju-si, Gangwon-do 26365
Korea, South

Re: K240196
Trade/Device Name: Bladeless Trocar (E05, E10, E11, E12, ES05, ES10, ES12)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: May 20, 2024
Received: May 20, 2024

Dear Bae Ji Hyeon :

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.06.18 08:49:59 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K240196

Device Name

Bladeless Trocar (E05, E10, E11, E12, ES05, ES10, ES12)

Indications for Use *(Describe)*

ENPOLE is a single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.

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.

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510(k) Summary

(ENPOLE® Bladeless Trocar)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: 18/01/2024

1. SUBMITTER

Submitter's Name: YUWONMEDITECH CO., LTD.
Submitter's Address: 103, 104, 108, 113, 114, 117, Donghwa Medical Instrument Complex, 147-1, Donghwagongdan, Munmak-eup, Wonju-si, Gangwon-do, Korea
Telephone Number: +82-33-743-0081
Fax: +82-33-743-0081

2. CONTACT PERSON

Byung-kyu, Park
Quality Management Representative

Ji-Hyeon, Bae
Manager, Regulatory Affairs

TEL. +82-33-743-0081
E-Mail: bkpark@yuwonmeditech.com, jhbae@yuwonmeditech.com
Address: 103, 104, 108, 113, 114, 117, Donghwa Medical Instrument Complex, 147-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea

3. DEVICE INFORMATION

Trade Name: ENPOLE® Bladeless Trocar
Common Name: Bladeless Trocar
Product Code: GCJ
Classification Regulation: 21 CFR 876.1500
Device Class: Class II
Classification Panel: General and Plastic Surgery

4. PREDICATE DEVICE

The proposed ENPOLE® Bladeless trocars are substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Decision Date
CORE-Trocar	INCORE CO.,LTD.	K211148	05/19/2022

5. DEVICE DESCRIPTION

The Bladeless Trocar is a sterile single patient use instrument consisting of a sleeve in sizes from 5 mm to 12 mm diameters. The trocar sleeve for the devices contains two seal, an outer integrated self-adjusting seal that accommodates instruments ranging from 5 mm to 12.5 mm in diameter where indicated and an internal seal. Together, these seal minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5 mm trocar sleeve accommodates only 5 mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation.

Bladeless trocar is access into the abdomen of laparoscopy that is particular to the insertion of surgical instruments through small incisions. The sleeve penetrated into the intra- abdominal by the obturator is inserted and fixed in the abdominal wall, which is a principle that allows laparoscopy to be performed at a constant abdominal pressure state by keeping it sealed to the outside of the human body.

6. INDICATIONS FOR USE

ENPOLE Trocar is a single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.

7. SUBSTANTIAL EQUIVALENCE

The proposed ENPOLE® Bladeless Trocars have the same technology and functional characteristics as the predicate systems. The intended use, operating principles, performance specifications, sterilization and expiration dating of the subject device are the same as the predicate device.

7.1 Comparison Table

Descriptive Information	Subject Device	Predicate Device (K211148)
Manufacturer	YUWONMEDITECH CO., LTD.	INCORE CO., LTD.
Model Name	ENPOLE	CORE-TROCAR
Classification Regulation	21 CFR 876.1500	21 CFR 876.1500
Product Code	GCJ	GCJ
Classification	Class II	Class II
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery
Indications for Use	ENPOLE Trocar is a single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.	A single-use medical device to have a port to insert endoscopic instruments for endoscopic procedures.
Compared elements	Cannula Tip of obturator	Cannula Tip of obturator

Picture		
Dimension	Diameter: 5, 10, 11, 12 mm	Diameter: 2 ~ 12 mm
	Length: 60, 75,100 mm	Length: 100 ~ 150 mm
Sterilization	EO Sterilization (S.A.L. 10^{-6})	EO Sterilization (S.A.L. 10^{-6})
Shelf Life	5 years	3 years
Single use / Re-use	Single-use	Single-use

8. PERFORMANCE DATA

Test	Criteria	Standard	Result
Appearance	Internal standard	Internal standard	Pass
Dimension	Internal standard	Internal standard	Pass
Air leakage	Internal standard	Internal standard	Pass
Seal test	Internal standard	Internal standard	Pass
Instrument compatibility test	Internal standard	Internal standard	Pass

9. NON-CLINICAL TEST

- Packaging Validation
- E.O sterilization Validation
- Bioburden Test, E.O gas residue Test
- Shelf-Life Test/Real-time Sterility Test
- Transport Validation
- Biocompatibility

10. Conclusion

Based upon the test results, the proposed ENPOLE® Bladeless Trocars are substantially equivalent in performance to the predicate devices cleared to market via 510(k) K211148. The proposed ENPOLE® Bladeless Trocars do not introduce any new issues of safety and effectiveness.