April 9, 2018

Fengh Medical Co., Ltd.
Jun Zhou
Regulatory Affairs Manager
D3 No. 6 Dongsheng West Road,
Jiangyin National High-tech Zone
Jiangyin, 214437 Cn

Re: K180208
Trade/Device Name: Disposable Endoscopic Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 8, 2018
Received: February 12, 2018

Dear Jun Zhou:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180208

Device Name
Disposable Endoscopic Trocar

Indications for Use *(Describe)*
The Disposable Endoscopic Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

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 OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. Date Prepared [21 CFR 807.92(a)(1)]

02/20/2018

2. Submitter's Information [21 CFR 807.92(a)(1)]

Company Name: Fengh Medical Co., Ltd.
Company Address: D3 No.6 Dongsheng West Road, Jiangyin National High-tech Zone, 214437 Jiangsu, China
Contact Person: Jun Zhou
Phone: 86 - 15906171661
Email: zj_fenghmedical@163.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: Disposable Endoscopic Trocar
Common Name: General & Plastic Surgery
Product Code: GCJ
Regulation Number: 21 CFR 876.1500
Device Class: II

4. Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]

The identification of predicates within this submission is as follow:

Predicate I

Manufacturer: Ethicon Endo-Surgery, Inc
Trade Name: ENDOPATH III Bladeless Trocars
ENDOPATH III Blunt Tip Trocars
ENDOPATH III Dilating Tip Trocars
Common Name: ENDOPATH III Trocar System
Product Code: GCJ
Classification Name: General& Plastic Surgery
Regulation Number: 21 CFR 876.1500
Classification: Class II
FDA 510 (k) Number: K032676

5. Description of the Device [21 CFR 807.92(a)(4)]

The Fengh Medical Disposable Endoscopic Trocar has applications in abdominal, thoracic and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and econdary insertions.

A Disposable Endoscopic Trocar is mainly composed of Obturator Handle, Outer Seal Release Lever, Trocar Stability Sleeve, Obturator Locking Button, Trocar Stability Sleeve, etc. Materials being used include Stainless 12Cr18Ni9, Stainless 06Cr19Ni10, ABS plastic, PC. All the components of Disposable Endoscopic Trocar are evaluated by cytotoxicity test, sensitization test, intracutaneous mucosa stimulation test, Systemic toxicity(acute) test and Pyrogenicity test. Therefore, it will not cause bad stimulations, allergic reactions or other harm to human tissue or mucosa. Furthermore, no toxic substances will be separated out during the use of Disposable Endoscopic Trocar.

Endoscopic surgery is conducted through a cannula that extends across the abdominal wall and provides channels where instruments, such as scopes, retractors and staplers, can be inserted to perform surgery. As part of this procedure, the abdominal cavity is inflated with an insufflation gas, such carbon dioxide, to maintain the abdomen in a distended state and provide increased instrument maneuvering capability within the cavity. Valves are typically provided in the trocars to form seals around the instruments to prevent leakage of the insufflation gas.

6. Intended Use [21 CFR 807.92(a)(5)]

The Disposable Endoscopic Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

7. Technological Characteristic [21 CFR 807.92(a)(6)]

Optical Entry

- Visualization is optically guided by a 0° endoscope
- Enables visualization of tissue layers during insertion

Durable Universal Seal

- No reducer caps needed
- Maintains insufflation

Camera Scope-Locking Tab

- Holds camera locked in place during visually guided entry
- Helps provide visual clarity and protects camera from scratching or falling out

Integrated Stability Thread Design

- Maximizes abdominal wall retention for minimal trocar slip-outs

Bladeless Optical Tip

- Separates, rather than cuts, along tissue fibers
- Reduced risk of abdominal wall injuries

8. Testing

Table 1	**Tests**
Clinical	Not Applicable
Non-Clinical Testing:	Sterility Test
	Peel Strength
	Flexibility
	Fitness
	Leakage
	Roughness
	Dimension
	Appearance
	Insertion & Cannula Stability
	Trocar sleeve retention force
	Endoscope Visualization Quality
Biocompatibility Testing:	In Vitro Cytotoxicity Test
	Skin Sensitization Test
	Intracutaneous reactivity Test
	Acute Systemic Toxicity
	Pyrogen Test

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Table 2	Proposed Device	Predicate Device
Device Name	Disposable Endoscopic Trocar	ENDOPATH@ III Bladeless Trocars
Trade Name	Disposable Endoscopic Trocar	ENDOPATH@ III Bladeless Trocars

		ENDOPATH@ III Blunt Tip Trocars ENDOPATH@ III Dilating Tip Trocars
Device Classification	II	II
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Product Code	GCJ	GCJ
Intended Use	The Disposable Endoscopic Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.	The ENDOPATH III Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions. The ENDOPATH III Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments. The ENDOPATH III Blunt Tip Trocar has applications in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments.
Sizes (Diameter)	5mm	5mm
	N/A	8mm
	10mm	N/A
	N/A	11mm
	12mm	12mm
	N/A	15mm
Size (Length)	N/A	75mm
	100mm	100mm
	N/A	150mm
Principles of	During the operation, the trocar	During the operation, the

operation	sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for endoscopic instruments.	trocar sleeve and the obturator are used together. The surgeon uses the obturator to expand the incision of the abdomen and penetrates the trocar sleeve through the abdominal surface of the human body into the abdominal cavity, thereby delivering gas to the abdominal cavity and establishing a path of entry for endoscopic instruments.
Main Components	Obturator	Obturator
	Obturator Handle	Obturator Handle
	Scope locking Cam (Except FLPC5, FLPC10, FLPC12)	Scope locking Cam (housed in obturator handle)
	Obturator Locking Button (housed in obturator handle)	Obturator Locking Button (housed in obturator handle)
	Outer Seal	Outer Seal
	Outer Seal Release Lever (Except FLPC5,FLPC10, FLPC12)	Outer Seal Release Lever
	Stopcock	Stopcock
	Trocar Smooth Sleeve	Trocar Smooth Sleeve
	Trocar Stability Sleeve	Trocar Stability Sleeve
	Optical Element	Optical Element
	Bladeless Tip	Bladeless Tip
	N/A	Bladeless Tip Symbol
	N/A	Pistol Handle
Patient Contacting Structure	Obturator Trocar Smooth Sleeve Trocar Stability Sleeve Optical Element Bladeless Tip	Obturator Trocar Smooth Sleeve Trocar Stability Sleeve Optical Element Bladeless Tip
Patient Contacting Material	ABS-1, MN, 095-30-16-15/PC/Stainless 12Cr18Ni9 (Except FLPC5, FLPC10, FLPC12)/Stainless 06Cr19Ni10 (Except FLPC5, FLPC10, FLPC12)	N/A
Sterilization	Sterilized using Irradiation	N/A
Application Sites	Abdominal	Abdominal
	Thoracic	Thoracic
	Gynecologic	Gynecologic

Number of Ports	1	1
Single Use	Yes	Yes
Obturator & Cannula Compatibility	Sleeve and Obturator should fit well without any interference. Max clearance between sleeve and Obturator: D≤0.3mm The tip of Obturator should be fully out of sleeve when fit.	N/A
Insertion &Cannula Stability	When the obturator pulled out Trocar sleeve, the friction should not exceed 5N.	N/A
Trocar System Puncture Performance	Obturator roughness Ra must not be bigger than 0.4μm.	N/A
Trocar sleeve retention force	Apply a pressure of 5N ± 1N on both sides of the thread area, the pull-out force of the sleeve should not less than 10N.	N/A
Air Leakage as a whole device	There should be no leakage under 4kPa pressure between stopcock and sealing cap.	N/A
Air Leakage with obturator withdrawed	Choke valve should have good gas blocking performance. Bubbles should be less than 20 under 4KPa pressure.	N/A
Endoscope Visualization Quality	Accommodate an appropriately sided 0º endoscope.	N/A
Biocompatibility	In Vitro Cytotoxicity Test	N/A
	Skin Sensitization Test	N/A
	Intracutaneous reactivity Test	N/A
	Acute Systemic Toxicity	N/A
	Pyrogen Test	N/A

10. <u>Conclusion [21 CFR 807.92(b)(3)]</u>

The Disposable Endoscopic Trocar substantially equivalent to predicate device because both devices use identical technology and same intended use, also testing standards are identical with the predicates. The differences between both devices are insignificant in terms of safety and effectiveness.