May24, 2024

M/s. Meril Endo Surgery Private Limited.
Chetan Patel
Manager - Regulatory Affairs
Third Floor, E1-E3, Meril Park, Survey No. 135/2/B & 174/2,
Muktanand Marg, Chala
Vapi, Gujarat 396191
India

Re: K233386
Trade/Device Name: Monik™ - Disposable Endoscopic Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 28, 2023
Received: October 2, 2023

Dear Chetan Patel:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.05.24 08:23:11 -04'00'

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

K233386

Device Name

Monik™ - Disposable Endoscopic Trocar

Indications for Use *(Describe)*

The Monik™ - 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

Meril
Endo Surgery

I. *SUBMITTER*

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Primary Correspondent Information

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Manager – Regulatory Affairs
E-mail: chetan.patel@merillife.com

Date Prepared: September 30th, 2023

II. *SUBJECT DEVICE*

Trade / Proprietary Name	**Monik™** - Disposable Endoscopic Trocar
Common Name	Disposable Endoscopic Trocar
Classification	Endoscope and Accessories
Regulatory Class	II
Product Code	GCJ
Regulation Number	21 CFR Part 876.1500
Review Panel	General & Plastic Surgery

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III. *PREDICATE DEVICE*

Subject device	Predicate device		
	Trade Name	**Manufacturer**	**510 (K) No.**
Monik™ - Disposable Endoscopic Trocar	ENDOPATH® III Bladeless Trocars (Primary Predicate)	Ethicon Endo-Surgery, Inc.	K032676
	Disposable Bladeless Trocar	Changzhou Xin Neng Yuan Medical Stapler Co., Ltd	K190029

IV. *Device Description*

The Disposable Endoscopic Trocar is sterile single patient use instrument consisting of a radiolucent sleeve and obturator in sizes 5mm, 10mm, 12mm, 12mm long and 15mm diameter. The obturator contains a clear tapered optical element. The 10mm, 12mm and 15mm diameter obturators accommodate an appropriately sided 0° endoscope and provide visibility of individual tissue layers during insertion. The trocar sleeves for the 5 mm, 10 mm, 12mm, 12mm long and 15 mm devices contain two seals. An outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 mm to 15 mm in diameter where indicated and an internal seal. Together these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation.

V. *Indications for 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.

VI. *Substantial Equivalence*

The Monik™ Trocar is substantially equivalent to marketed predicate device with respect to intended use and technological characteristics. The Monik™ Trocar operates on the same principle as predicate devices. The results demonstrated that the subject device is as safe and as effective as the predicates.

Substantial equivalence is based on the following parameters:

1. Intended use
2. Principle of Operation
3. Product design

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4. Single use
5. Sterilisation method
6. Packaging
7. Performance
8. Biocompatibility

VII. *Preclinical Data*

Performance Tests

The Monik™ Disposable Endoscopic Trocar was subjected to the performance testing and biocompatibility testing of the Trocar material in accordance to EN ISO 10993-1:2020 has been performed to further ensure substantial equivalence to the predicate devices. The safety and effectiveness of the Monik™ Disposable Endoscopic Trocar has been evaluated for the following performance and safety requirements.

1. Dimensions
2. Fitness Property
3. Confirmation firmness test
4. Flexibility
5. Air blocking & sealing test
6. Trocar puncture & removal test
7. Sterility USP <71>
8. Biocompatibility as per ISO 10993-1

Biocompatibility

The biocompatibility evaluation for Monik™ Trocar was conducted in accordance with Guidance document 'Use of International Standard ISO 10993-1, ''Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'' September 8, 2023 and International Standards ISO 10993-1 "Biological evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process" as recognized by FDA. Based on attachment A (Table A.1) of the FDA guidance, following tests were identified and performed.

- In vitro cytotoxicity test
- Skin sensitization test
- Intracutaneous reactivity test

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The test results suggest that the subject device is biocompatible.

Sterilization

Monik™ Trocar is sterilized by Ethylene Oxide Method as per EN ISO 11135:2014. (Medical Devices – Validation & Routine Control of Ethylene Oxide Sterilization.

The Ethylene oxide sterilization process is validated as per ISO 11135. The method used for ethylene oxide sterilization validation was overkill (half-cycle approach) method in a fixed chamber. Ethylene oxide residuals were tested and met ISO 10993-7 requirements.

The sterilization processes have demonstrated a sterility assurance level of 10^{-6}.

The maximum residual levels after Ethylene Oxide sterilization are as under.

- Ethylene Oxide: 4 mg in first 24 hr & 60 mg in first 30d
- Ethylene Chlorohydrins: 9 mg in first 24 hr & 60 mg in first 30d
- Ethylene Glycol: 9 mg in first 24 hr & 60 mg in first 30d

Packaging & Shelf life

Following packaging and shelf life study was conducted to ensure package integrity throughout the shelf life.

- Packaging validation as per ISO 11607
- Shelf life validation as per ICH Q1A (R2) & ISO 11607
- Transportation Study as per ASTM D 999 & ASTM D 5276

VIII. *Conclusion*

Monik™ Disposable Endoscopic Trocar is substantially equivalent to currently marketed device and present no substantial differences in design, material, intended use and function to predicate device.

The performance, biocompatibility, sterilization, packaging and shelf life study conducted on Monik™ Disposable Endoscopic Trocar demonstrated the device is as safe and as effective as the predicate device. Hence, Monik™ Disposable Endoscopic Trocar will perform as intended in the specified use conditions.