October 6, 2017

Renovo, Inc.
% Mr. Robert Packard
President
Medical Device Academy, Inc.
345 Lincoln Hill Rd.
Shrewsbury, Vermont 05738

Re: K172097
Trade/Device Name: Reprocessed Ethicon Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NLM
Dated: October 3, 2017
Received: October 3, 2017

Dear Mr. Packard:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K172097

Device Name
Reprocessed Ethicon Bladeless Trocars
Reprocessed Ethicon Universal Trocar Sleeves

Indications for Use *(Describe)*
The Reprocessed Ethicon Bladeless Trocars are intended for use in thoracic, gynecologic, laparoscopic and other abdominal or minimally invasive surgical procedures to establish a path of entry for endoscopic or minimally invasive instruments. The reprocessed optical trocar may be used with or without visualization for primary and secondary insertions.

The Reprocessed Ethicon Universal Trocar Sleeves are intended for use in thoracic, gynecologic, laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

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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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Reprocessed Single-Use Ethicon Trocars Device Models Subject to Clearance

Model Name	OEM Model #	Shaft Diameter	Shaft Length	Sleeve
ENDOPATH XCEL® Bladeless Trocars	B5LT	5mm	100mm	Stability
	B5SP	5mm	75mm	Smooth
	B5ST	5mm	75mm	Stability
	B5LP	5mm	100mm	Smooth
	B5LPH	5mm	100mm, handled	Smooth
	B5XT	5mm	150mm	Stability
	B8LT	8mm	100mm	Stability
	B12LT	12mm	100mm	Stability
	B12LTH	12mm	100mm, handled	Stability
	B12SRT	12mm	75mm	Stability
	B12XT	12mm	150mm	Stability
	B15LT	15mm	100mm	Stability
	B11LP	11mm	100mm	Smooth
	B11LPH	11mm	100mm, handled	Smooth
	B11LT	11mm	100mm	Stability
	B11LTH	11mm	100mm, handled	Stability
	B12LP	12mm	100mm	Smooth
	B12LPH	12mm	100mm, handled	Smooth

Model Name	OEM Model #	Shaft Diameter	Shaft Length	Sleeve
ENDOPATH XCEL® Universal Sleeves	CB5LT	5mm	100mm	Stability
	CB5ST	5mm	75mm	Stability
	CB11LT	11mm	100mm	Stability
	CB12LT	12mm	100mm	Stability

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

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Date Prepared: October 2, 2017

III. DEVICE

Name of Device:	Reprocessed Ethicon Trocar
Classification Name:	Laparoscope, General & Plastic Surgery, Reprocessed
Regulation:	21 CFR 876.1500
Regulatory Class:	Class II
Product Classification Code:	NLM

IV. PREDICATE DEVICE

Predicate Manufacturer:	Ethicon Endo-Surgery, LLC
Predicate Trade Name:	ENDOPATH® XCEL® Trocar with OPTIVIEW™ Technology
Predicate 510(k):	K122511

No reference devices were used in this submission.

V. DEVICE DESCRIPTION

A trocar is a sterile device used in a variety of endoscopic procedures to establish and maintain a port of entry for surgical tools. Trocars consists of three primary components; the cannula which allows access into the abdominal cavity during the procedure; the seal, located at the top of the cannula allows instruments to pass through the cannula while preventing loss of pneumoperitoneum when instruments are inserted and withdrawn from the port, and; the obturator which is a mechanism that allows the cannula to penetrate the abdomen. The trocars contained in this submission are bladeless. There are also various configurations of diameter and length, but all models have the same basic design, materials, and technological characteristics.

VI. INDICATIONS FOR USE

The Reprocessed Ethicon Bladeless Trocars are intended for use in thoracic, gynecologic, laparoscopic and other abdominal or minimally invasive surgical procedures to establish a path of

entry for endoscopic or minimally invasive instruments. The reprocessed bladeless optical trocar may be used with or without visualization for primary and secondary insertions.

The Reprocessed Ethicon Universal Trocar Sleeves are intended for use in thoracic, gynecologic, laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE OEM PREDICATE DEVCE

The fundamental technological characteristics of the subject device are identical to the predicate (OEM). The following characteristics were compared between the subject device and the OEM device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have the same indications for use. The bladeless trocars are indicated for use in thoracic, gynecologic, laparoscopic and other abdominal or minimally invasive surgical procedures to establish a path of entry for endoscopic or minimally invasive instruments. The reprocessed bladeless optical trocar may be used with or without visualization for primary and secondary insertions. The universal trocar sleeves are indicated for use in thoracic, gynecologic, laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.
- Materials – The materials in the subject device are identical to the predicate with exception to the lubricant. The lubricants are not identical, but are equivalent in functional and biocompatible performance.
- Design – The predicate and subject devices have identical designs.
- Energy Source – Neither the predicate nor the subject device require power or an energy source.
- Performance Testing – The subject devices are reprocessed versions of the predicate (OEM) devices. The OEM devices are performance-tested cleared medical devices; therefore the performance testing consisted of side-by-side testing of the reprocessed devices to an identical new OEM device. This testing included seal drag, seal leakage, insertion, fixation, and removal testing.
- Cleaning Validation – While it is very important to test the performance of the reprocessed device to ensure it performs as new; an important part of the risk management of a reprocessed device is the need to ensure cleanliness. A cleaning validation was performed to ensure that the reprocessing steps thoroughly cleaned and sanitized the devices so that they were as clean as a new OEM device.

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

<u>Performance Testing</u>

- Functional
  - Seal Drag
  - Seal Leakage
  - Insertion, Fixation, and Removal Force Test
- Product Stability
  - Shelf Life Testing 1-year Accelerated Aging

<u>Cleaning Validation</u>

- Residual Protein and Hemoglobin
- Visual Inspection

- Cleaning Performance Qualification

Sterilization and Packaging

- EtO Sterilization Testing
- Simulated Shipment Testing

Biocompatibility Testing

- Cytotoxicity
- Irritation and Sensitization
- Acute Systemic
- EtO Residuals Testing
- Material Mediated Pyrogenicity

Electrical Safety and EMC Testing

Electrical safety and EMC testing were not applicable.

Animal Testing

Animal performance testing was not required to demonstrate safety and effectiveness.

Clinical Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the Reprocessed Ethicon Trocar. Substantial equivalence is based upon benchtop performance testing.

IX. CONCLUSIONS

Side by side testing ensured that the reprocessed trocars performed equivalently to the same device new from the OEM. Cleaning validations ensured that the devices are reprocessed and cleaned to the condition of a new OEM device. Therefore, based on a comparison of technological characteristics, indications for use, and performance comparison data, it can be concluded that the proposed Reprocessed Ethicon Trocars are substantially equivalent to the OEM predicate device.