July 31, 2020

Stryker Sustainability Solutions
Ms. Ramona Kulik, BS MET
Staff Specialist, Regulatory Affairs
1810 W. Drake Drive
Tempe, Arizona 85283

Re: K201511
Trade/Device Name: Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT)

Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NLM
Dated: June 2, 2020
Received: June 5, 2020

Dear Ms.Kulik:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 Chen, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201511

Device Name
Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT)

Indications for Use *(Describe)*
The Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT) have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The Bladeless Trocars 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.

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Reprocessed Device Models Included in Submission K201511:

OM	Model Numbers	Description	Sleeve Style	Shaft Diameter	Shaft Length
Ethicon	B5LT	XCEL Bladeless Trocar	Stability	5mm	100mm
Ethicon	B5ST	XCEL Bladeless Trocar	Stability	5mm	75mm
Ethicon	B11LT	XCEL Bladeless Trocar	Stability	11mm	100mm
Ethicon	B12LT	XCEL Bladeless Trocar	Stability	12mm	100mm
Ethicon	H12LP	XCEL Blunt Tip Trocar	Smooth	12mm	100mm
Ethicon	D5LT	XCEL Dilating Tip Trocar	Stability	5mm	100mm
Ethicon	D5ST	XCEL Dilating Tip Trocar	Stability	5mm	75mm
Ethicon	D11LT	XCEL Dilating Tip Trocar	Stability	11mm	100mm
Ethicon	D12LT	XCEL Dilating Tip Trocar	Stability	12mm	100mm
Ethicon	2B5ST	XCEL Bladeless Trocar w/Optiview Technology	Stability	5mm	75mm
Ethicon	2B5LT	XCEL Bladeless Trocar w/Optiview Technology	Stability	5mm	100mm
Ethicon	2D5ST	XCEL Dilating Tip Trocar w/Optiview Technology	Stability	5mm	75mm
Ethicon	2D5LT	XCEL Dilating Tip Trocar w/Optiview Technology	Stability	5mm	100mm
Ethicon	CB5LT	XCEL Trocar Sleeve	Stability	5mm	100mm
Ethicon	CB5ST	XCEL Trocar Sleeve	Stability	5mm	75mm
Ethicon	CB11LT	XCEL Trocar Sleeve	Stability	11mm	100mm
Ethicon	CB12LT	XCEL Trocar Sleeve	Stability	12mm	100mm
Ethicon	2CB5LT	XCEL Universal Stability Sleeve w/Optiview Technology	Stability	5mm	100mm
Ethicon	2CB5ST	XCEL Universal Stability Sleeve w/Optiview Technology	Stability	5mm	75mm

K201511

510(k) SUMMARY

Submitter:

Stryker Sustainability Solutions
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Tempe, Arizona 85283

Contact:

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Date of Preparation: July 30, 2020

Name of Device:

Trade/Proprietary Name: Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT,CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT)

Common Name: Trocars and Sleeves

Classification Information: Laparoscope, General and Plastic Surgery, Reprocessed

Regulation Number: 876.1500

Product Code: NLM

Predicate Device:

510(k) Number	510(k) Title	Original Manufacturer
K032676	ENDOPATH III Bladeless Trocars	ETHICON ENDO-SURGERY, LLC
K122511	ENDOPATH XCEL TROCAR WITH OPTIVIEW TECHNOLOGY	ETHICON ENDO-SURGERY, LLC

Device Description:

The Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT) are sterile, single patient use instruments consisting of a radiolucent sleeve (cannula) and obturators in sizes ranging from 5-12 mm in diameter. There are three different obturators; Bladeless, Dilating Tip (Bladed) and Blunt Tip. The bladeless obturator contains a clear, tapered optical element, and when used with an endoscope provides visibility of individual tissue layers during insertion. The Dilating Tip (Bladed) obturator has a sharp, flat-bladed tip and spring-loaded shield. The shield is designed to cover the flat-bladed tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered. The Blunt Tip obturator has a blunt plastic tip which gently moves aside any viscera that may be adjacent to abdominal or thoracic wall.

The trocar sleeve contains two seals that accommodate instruments. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. Please note that the 5mm bladeless trocar cannula without Optiview Technology does not have the outer integrated self-adjusting seal and only accommodates 5mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Trocars with Optiview Technology incorporates a design enhancement that reduces the incidence of trocar induced endoscope lens smudging during endoscope insertion.

The Reprocessed Sleeves are sterile, single patient use devices with a radiolucent sleeve (cannula). The trocar sleeve contains two seals that accommodate instruments. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. Please note that the 5mm trocar cannula without Optiview Technology does not have the outer integrated self-adjusting seal and only accommodates 5mm instruments. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

The model numbers included in the scope of this submission are as follows:

OM	Model Numbers	Description	Sleeve Style	Shaft Diameter	Shaft Length
Ethicon	B5LT	XCEL Bladeless Trocar	Stability	5mm	100mm
Ethicon	B5ST	XCEL Bladeless Trocar	Stability	5mm	75mm
Ethicon	B11LT	XCEL Bladeless Trocar	Stability	11mm	100mm
Ethicon	B12LT	XCEL Bladeless Trocar	Stability	12mm	100mm
Ethicon	H12LP	XCEL Blunt Tip Trocar	Smooth	12mm	100mm
Ethicon	D5LT	XCEL Dilating Tip Trocar	Stability	5mm	100mm
Ethicon	D5ST	XCEL Dilating Tip Trocar	Stability	5mm	75mm
Ethicon	D11LT	XCEL Dilating Tip Trocar	Stability	11mm	100mm
Ethicon	D12LT	XCEL Dilating Tip Trocar	Stability	12mm	100mm

Ethicon	2B5ST	XCEL Bladeless Trocar w/Optiview Technology	Stability	5mm	75mm
Ethicon	2B5LT	XCEL Bladeless Trocar w/Optiview Technology	Stability	5mm	100mm
Ethicon	2D5ST	XCEL Dilating Tip Trocar w/Optiview Technology	Stability	5mm	75mm
Ethicon	2D5LT	XCEL Dilating Tip Trocar w/Optiview Technology	Stability	5mm	100mm
Ethicon	CB5LT	XCEL Trocar Sleeve	Stability	5mm	100mm
Ethicon	CB5ST	XCEL Trocar Sleeve	Stability	5mm	75mm
Ethicon	CB11LT	XCEL Trocar Sleeve	Stability	11mm	100mm
Ethicon	CB12LT	XCEL Trocar Sleeve	Stability	12mm	100mm
Ethicon	2CB5LT	XCEL Universal Stability Sleeve w/Optiview Technology	Stability	5mm	100mm
Ethicon	2CB5ST	XCEL Universal Stability Sleeve w/Optiview Technology	Stability	5mm	75mm

Indications for Use:
The Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST,CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT) have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The Bladeless Trocars may be used with or without visualization for primary and secondary insertions.

Substantial Equivalence Table of Reprocessed Endoscopic Trocars and Sleeves and Endopath Bladeless Trocars, Endopath Blunt Tip Trocars, Endopath Dilating Tip Trocars and Ehicon Endopath XCEL Trocars (Bladeless, Blunt Tip, Dilating Tip) with Optiview Technology:

Characteristic	**Ethicon Endo-Surgery (K032676)** **Endopath Bladeless Trocars** **Endopath Blunt Tip Trocars** **Endopath Dilating Tip Trocars**	**Ethicon Endo-Surgery** **Ethicon Endopath XCEL Trocars** **Bladeless, Blunt Tip, Dilating Tip w/Optiview Technology** **K122511**	**Stryker Sustainability Solutions** **Reprocessed Endoscopic Trocars and Sleeves**
Indications for Use	The Endopath Bladeless 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	The Endopath XCEL Bladeless Trocar with Optiview Technology has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may	The Reprocessed Endoscopic Trocars and Sleeves have applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments, The Bladeless Trocars may be used with or

		primary and secondary insertions. The Endopath Blunt Tip Trocar has applications in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments. The Endopath Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy ant other abdominal procedures to establish a path of entry for endoscopic instruments.	be used with or without visualization for primary and secondary insertions. The Endopath XCEL Blunt Tip Trocar with Optiview Technology has applications in thoracic, gynecologic, laparoscopic and other abdominal procedures to establish a path of entry for minimally invasive instruments. The Endopath XCEL Dilating Tip Trocar with Optiview Technology has applications in thoracic, gynecologic laparoscopy ant other abdominal procedures to establish a path of entry for endoscopic instruments. The Endopath XCEL Universal Trocar Stability Sleeve with Optiview Technology has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.	without visualization for primary and secondary insertions.
Contra-indications		This device is not intended for use when minimally invasive techniques are contraindicated.	The device is not intended for use when minimally invasive techniques are contraindicated.	Any uses generally contraindicated for minimally invasive techniques.
Materials				
Material composition	Cannula Shaft	Polycarbonate	Polycarbonate	Polycarbonate
	Cannula Hub/Housing	Polycarbonate	Polycarbonate	Polycarbonate
	Cannula Seal	Polycarbonate	Polycarbonate	Polycarbonate
	Cannula Gasket	Rubber	Rubber	Rubber
	Stopcock Valve	Polycarbonate	Polycarbonate	Polycarbonate
	Stopcock Lever	Polyethylene	Polyethylene	Polyethylene
	Obturator Shaft	Stainless Steel (300 series) Polycarbonate (Blunt Tip Trocar- H12LP)	Stainless Steel (300 series) Polycarbonate (Blunt Tip Trocar-H12LP)	Stainless Steel (300 series) Polycarbonate (Blunt Tip Trocar- H12LP)
	Obturator Tip	Polycarbonate	Polycarbonate	Polycarbonate
Sterility		Sterile by Irradiation	Sterile by Irradiation	Sterile by Ethylene Oxide
Uses		Single-patient use	Single-patient use	Single-patient use

Pyrogenicity	No	No	No

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed Endoscopic Trocars and Sleeves are identical to the predicate devices. The mechanism of action of Reprocessed Endoscopic Trocars and Sleeves are identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions reprocessing of Endoscopic Trocars and Sleeves includes removal of adherent visible soil and decontamination and replacement of the stability plug suture clips and stability plug clamp. Each individual Endoscopic Trocars and Sleeves are tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:
Bench and laboratory testing were conducted to demonstrate performance (safety and effectiveness) of Reprocessed Endoscopic Trocars and Sleeves. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Testing
  Device Aesthetics
  Peak Insertion Force
  Stability Plug Clip Integrity
  Stability Plug Clamp Integrity
  Trocar Leak Test
  Obturator Engagement
  Cannula Housing Integrity
  Obturator Housing Integrity
  Cannula Sleeve Integrity
  Insertion/Withdrawal Forces – Obturator to Cannula
  Device Integrity
  Peak Insertion Force
  Obturator Engagement
  Shield Lock Engagement Force
  Blade Shield Engagement
- Packaging Validation

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

The Reprocessed Endoscopic Trocars and Sleeves are reprocessed no more than one (1) time. Each reprocessed device is tracked with a Stryker pad print on the device indicating the device has been reprocessed one (1) time. Once the device reaches the maximum number or reprocessing cycles, it is rejected and taken out of service. Reprocessing is conducted only by Stryker Sustainability Solutions. Stryker Sustainability Solutions restricts its reprocessing to exclude devices previously reprocessed by other companies.

Conclusion:

The results of bench and laboratory testing demonstrate that the Reprocessed Endoscopic Trocars and Sleeves (B11LT, B12LT, B5LT, B5ST, CB11LT, CB12LT, CB5LT, CB5ST, D11LT, D12LT, D5LT, D5ST, H12LP, 2B5LT, 2B5ST, 2D5LT, 2D5ST, 2CB5ST, 2CB5LT) are at least as safe and effective and perform as well as the identified legally marketed predicate devices as described herein.