July 18, 2018

KARL STORZ Endoscopy-America, Inc.
AnnaLisa Smullin
Regulatory Engineer
2151 E. Grand Avenue
El Segundo, California 90245

Re: K180977
Trade/Device Name: KARL STORZ New Generation Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 8, 2018
Received: June 11, 2018

Dear AnnaLisa Smullin:

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180977

Device Name
KARL STORZ New Generation Trocars

Indications for Use *(Describe)*
KARL STORZ New Generation Trocars are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

K180977

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	AnnaLisa Smullin Regulatory Engineer Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	July 9, 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ New Generation Trocars Classification Name: Laparoscope, General & Plastic Surgery
Regulatory Class:	II
Product Code:	GCJ
Regulation:	21 CFR 876.1500
Predicate Device:	Primary Predicate Device: KARL STORZ Trocars (K940347) The predicate device has not been subject to a design-related recall.
Device Description:	The KARL STORZ New Generation Trocars provide a port of entry during endoscopic and laparoscopic procedures in pediatric and adult patients. The New Generation Trocars are available in diameters 2.5mm to 13.5mm and consist of a cannula, trocar, and a valve seal. The trocars combine single-use and reusable components since the valve seal is single use while the cannula and trocar are reusable components. The trocars are color coded by size and are available with pyramidal, conical, or conical-blunt tips. Reducers can be used to reduce the size of the trocar to accommodate a smaller instrument without losing pneumoperitoneum.
Intended Use:	To create and maintain a port of entry.
Indications For Use:	KARL STORZ New Generation Trocars are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.

Technological Characteristics:

Comparison Table: Subject vs. Predicate Device

	Subject Device KARL STORZ New Generation Trocars	Predicate Device, K940347 KARL STORZ Trocars
Indication for Use		
Indications for Use	Intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.	Intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy to create and maintain a port of entry.
Product Code	GCJ	GCJ
Target Population	Adult and pediatric general population	Adult and pediatric general population
Physical Characteristics		
Diameter	2.5-13.5 mm	3.3-15 mm
Length	5 or 10 cm	5-16 cm
Tip Design	Pyramidal, conical, blunt	Pyramidal, conical, blunt
Method of Action	Manual Insertion	Manual Insertion
Trocar Material	Stainless Steel	Stainless Steel
Cannula Material	Stainless Steel	Stainless Steel
Trocar Housing Material	PEEK (Polyether Ether Ketone)	Stainless Steel
Cleaning and Sterilization Methods		
Reusable Components	Trocar, Cannula, Reducer	Trocar, Cannula, Valve, Reducer
Cleaning	Manual	Manual
Sterilization	Steam	Steam, EtO
Sterile Single-Use Components	Valve Seals	None

Non-Clinical Performance Data:

Bench verification performance testing has been performed for the following parameters:

- Seal Leak Test
- Seal Leak Test while Under Torque
- Instrument Insertion and Retention Test
- Penetration Force
- Compression Testing of the Cannula
- Bending Testing of the Cannula
- Torsional Testing of the Cannula

Biocompatibility evaluation was performed to:

- ISO 10993

Sterility of the Reusable Components was validated in accordance with:

- ISO 11135

Sterility of the Sterile Single Use Components was validated in accordance with:

- ISO 11135
- ISO 10993
- ISO 11138

	• ISO 11737 Packaging for the Sterile Single Use Components was validated to: • ISO 11607 The subject device does not require electromagnetic compatibility, electrical safety, or software validation documentation.
Clinical Performance Data:	Clinical testing was not required to demonstrate substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence.
Medical Literature:	The following real world evidence (literature) was used to support the use of the KARL STORZ New Generation Trocars in a pediatric population as well as to demonstrate the safety and effectiveness of the subject device and its substantial equivalence to the predicate: • Blinman, T. & Ponsky, T. Pediatric Minimally Invasive Surgery: Laparoscopy and Thoracoscopy in Infants and Children. Pediatrics 130, 539–549 (2012). • Mitul, A. R. & Sarin, Y. K. Minimal Access Surgery in Neonates. J. Neonatal Surg. 6, (2017). • Slater, B. J. & Rothenberg, S. S. Minimally Invasive Approaches to GERD and Hiatal Hernia in Children. The SAGES Manual of Pediatric Minimally Invasive Surgery 315–326 (Springer, Cham, 2017). • Bruns, N. E. & DeRoss, A. L. Laparoscopic Management of Intussusception. In The SAGES Manual of Pediatric Minimally Invasive Surgery 443–450 (Springer, Cham, 2017). • Wei, J. & Feng, J. Laparoscopic treatment of liver diseases in children. Front. Med. 5, 388–394 (2011). • Ishimaru, T. & Iwanaka, T. Laparoscopy and Thoracoscopy. Operative Gen Surgery in Neonates and Infants 21–29 (Springer, Tokyo, 2016). • Hanna, G. B. & Cuschieri, A. Ergonomics of Task Performance in Endoscopic Surgery. 12 • Kurtz, Steven M., and John N. Devine. “PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants.” Biomaterials, vol. 28, no. 32, 2007, pp. 4845–4869. • Wei, Jia, and Jiexiong Feng. “Laparoscopic Treatment of Liver Diseases in Children.” Frontiers of Medicine, vol. 5, no. 4, 2011, pp. 388–394. • Bharathi, Ramanathan Saranga, et al. “Minimal Access Surgery of Pediatric Inguinal Hernias: a Review.” Surgical Endoscopy, vol. 22, no. 8, 2008, pp. 1751–1762. • Mattei, Peter. “Minimally Invasive Surgery in the Diagnosis and Treatment of Abdominal Pain in Children.” Current Opinion in Pediatrics, vol. 19, no. 3, 2007, pp. 338–343.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, KARL STORZ New Generation Trocars, performs as well as or better than the legally marketed predicate device.