January 18, 2019

KARL STORZ Endoscopy-America, Inc.
Nozomi Yagi
Sr. Regulatory Affairs Specialist
2151 E. Grand Avenue
EI Segundo, California 90245

Re: K183264
Trade/Device Name: Flex-THOR scope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 21, 2018
Received: November 23, 2018

Dear Nozomi Yagi:

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 and Part 809; 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.01.18 17:48:16 -05'00'

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)*
k183264

Device Name
Flex-Thor System

Indications for Use *(Describe)*
The Flex-THOR System is indicated for use in providing access to, and visualization of, the thoracic and abdominal cavities, to allow for the performance of various diagnostic and therapeutic surgical procedures.

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

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:	Nozomi Yagi Sr. Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	November 21, 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Flex-THOR System Classification Name: Endoscope and accessories (21 CFR Part 876.1500)
Regulatory Class:	II
Product Code and Common Name:	GCJ (Laparoscope, General & Plastic Surgery)
Guidance Document:	Not Applicable for GCJ product code
Recognized Consensus Standards:	Not Applicable for GCJ product code
Predicate and Reference Device(s):	Primary Predicate Device: Vibrynt Inc's VISTA Endoscope (K100533) Reference Device: XLTF-VAW Laparo-Thoraco Videoscope (K053382) ***The above predicate and reference device have not been subjected to any recall***
Device Description:	The Flex-THOR System includes two main components: (1) the Flex-THOR Scope (Part Number: 11292VS(U)A-THOR), and (2) the Camera Control Unit (CCU). The insertion shaft of the Flex-THOR Scope (Part Number: 11292VS(U)A-THOR) has an outer diameter of 2.9 mm and a working length of 675 mm with 8.5 Fr elliptical shaped

<table>
<tr><td></td><td>distal tip (major diameter of 3.2 mm and minor diameter of 2.4 mm). Users can access the 1.2 mm working channel through the Luer ports.</td></tr>
<tr><td>Intended Use:</td><td>The Flex-THOR System is intended for visualization purposes during abdominal and thoracic diagnostic and therapeutic procedures.</td></tr>
<tr><td>Indications For Use:</td><td>The Flex-THOR System is indicated for use in providing access to, and visualization of, the thoracic and abdominal cavities, to allow for the performance of various diagnostic and therapeutic surgical procedures.</td></tr>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Primary Predicate Devices
<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device, K100533</th></tr>
<tr><td>Type of Scope</td><td>Flexible</td><td>Same as the subject device</td></tr>
<tr><td>Distal End Diameter</td><td>3.2 mm x 2.4 mm</td><td>5.0 mm</td></tr>
<tr><td>Insertion Shaft Length</td><td>675 mm</td><td>530 and 890 mm</td></tr>
<tr><td>Type of Imager</td><td>CMOS</td><td>Fiber</td></tr>
<tr><td>Direction of View</td><td>0°</td><td>0°</td></tr>
<tr><td>Light Source</td><td>Internal LED</td><td>External</td></tr>
<tr><td>Cleaning</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Sterilization</td><td>Yes</td><td>Yes</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:
ANSI/AAMI ES:60601-1:2005
IEC 60601-1-2:2007
Reprocessing Validation Summary
The Flex-THOR Scope (Part Number: 11292VS(U)A-THOR) is provided non-sterile and is reusable. The users are required to reprocess it for initial and after each use. The subject device contacts intact mucosal membranes so it is a semi-critical device per Spaulding Classification. We performed validation activities for cleaning and sterilization according to the FDA Guidance. The reprocessing data submitted is in compliance with the following standards:
AAMI TIR 12:2010
ISO 15883-5:2005
AAMI TIR 30:2011
AAMI/ANSI/ISO 11737-1:2006/ (R)2011
ASTM E1837-96:2014</td></tr>
<tr><td>Clinical Performance Data:</td><td>Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.</td></tr>
<tr><td>Conclusion:</td><td>The conclusions drawn from the non-clinical performance data and comparison of device characteristics demonstrated that the subject device is as safe as and as effective as the predicate device. As such, we concluded that the substantial equivalence of the subject and the</td></tr>
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	predicate device has been met, and the differences between the subject and the predicate device do not raise new questions of safety and effectiveness.