DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 17, 2016

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

Re: K161112
Trade/Device Name: KARL STORZ Flexible Video-Neuro-Endoscope System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: August 18, 2016
Received: August 19, 2016

Dear Ms. 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. 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 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 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 yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K161112

Device Name
KARL STORZ Flexible Video-Neuro-Endoscope System

Indications for Use *(Describe)*
The KARL STORZ Flexible Video-Neuro-Endoscope System is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration.

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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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 Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	September 15, 2016
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Flexible Video-Neuro-Endoscope System Classification Name: Endoscope, Neurological (21 CFR Part 882.1480)
Regulatory Class:	II
Product Code:	GWG
Guidance Document:	Not Applicable for GWG product code
Recognized Consensus Standards:	Not Applicable for GWG product code
Predicate Device(s):	Predicate Device: KARL STORZ Endoscopy-America's KSEA Neuro-Fiberscope (K002788) The predicate device has not been subject to a design-related recall.
Device Description:	The Flexible Video-Neuro-Endoscope System is a videoscope indicated for viewing and providing access during cranial diagnostic and therapeutic procedures. The system consists of the KARL STORZ Flexible Video-Neuro-Endoscope (Model Number: 11161V) and the IMAGE1 SPIES Camera Control Unit (CCU), which has been cleared in K160044.KARL STORZ Flexible Video-Neuro-Endoscope's working shaft is 350 mm long with 8.5 Fr

	elliptical shaped distal tip (minor diameter is 2.4 mm and major diameter is 3.2 mm). The shaft has a Pellathane (polyurethane) cover and contains a PTFE working channel with an I.D. of 1.2 mm. The working channel length is 519 mm. Both instrument and irrigation ports have stopcocks, and there are no check valves or other restrictions to prevent the back flow within any point of the fluid path. The Video Neuroscope's direction of view is 0^o and the direction of view is 90^o. The distal tip houses the CMOS (complementary metal oxide semiconductor) imaging sensor, and the illumination is provided by two glass fiber light bundles, whose LED light source is located in the handpiece. In the handpiece of the KARL STORZ Flexible Neuro-endoscope, the user will find a deflection lever, which allows the distal tip to deflect 270 degrees in the UP/DOWN direction. Next to the deflection lever is three control buttons ("Select", "Left (Up)", and "Right (Down)") that provide a remote means for the user to interact with the IMAGE1 SPIES CCU and can be programmed to initiate specific functions such as white balance, image capture, zoom, and access to CCU setup menu. Once set by user, the control button assignment is retained after the system being switched on and off. LED (Light Emitting Diode) is integrated in the handpiece, and it is used to provide illumination of the anatomy under examination. The light is transmitted from the LED to the distal tip via two glass fiber light bundles. The raw data captured at the distal tip CMOS imaging sensor is converted to a standard NTSC (National Television System Committee) video signal by the printed circuit board (PCB), also housed in the handpiece.
Intended Use:	The KARL STORZ Flexible Video-Neuro-Endoscope System is intended for providing visualization and access during cranial diagnostic and therapeutic procedures.
Indications For Use:	The KARL STORZ Flexible Video-Neuro-Endoscope System is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration.

Technological Characteristics:

Comparison Table: Subject vs. Predicate Device

	Subject Device **Flexible Video-Neuro-Endoscope System**	**Primary predicate Device, K002788** **KSEA Neuro-Fiberscope**
Indication for Use		
Indications for Use	The KARL STORZ Flexible Video-Neuro-Endoscope System is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration.	The Neuro-Fiberscope is indicated for use in viewing the ventricles and cavities of the brain.
Design		
Type of scope	Flexible	Same as the subject device
Distal Tip Diameter	3.2 mm x 2.4 mm	3.6 mm
Outer Shaft Diameter	2.9 mm	3.7 mm
Working Shaft Length	350 mm	340 mm
Working Channel Diameter	1.2 mm	1.5 mm
Deflection (°)	Up: 270^0 Down: 270^0	Up: 180^0 Down: 100^0
Type of Imager	CMOS chip	Fiberscope
Material		
Shaft Material	Pellethane	polyurethane
Working Channel Material	PTFE	PTFE
Sterilization		
Sterilization	STERRAD NX “Advanced” Cycle STERRAD 100NX “Flex” or “DUO” Cycle STERIS SYSTEM 1E (SS1E) Standard Programmed Cycle V-PRO maX “Flexible” Cycle V-PRO 60 “Flexible” Cycle Ethylene Oxide (EtO) Gas	EtO Gas

Non-Clinical Performance Data:

Bench Testing Summary

Verification Test	Test Method Summary	Result
Optical	The test verified optical requirements for field of view, distortion and resolution.	Pass
White Balance and Color Accuracy	The test verified white balance and color accuracy.	Pass
Temporal and Spatial Noise	The test verified that the spatial noise and temporal noise does not exceed the limit specified in the device product specification under 'maximum gain' conditions.	Pass
Minimum Response	The test verified the minimum response measurement such that the sensitivity of the camera and the maximum intensity of the internal light source combine to ensure that the customer, under worst case distance-from-target conditions, has a bright enough scene to perform surgical functions.	Pass
AE Step Response	The test verified that when the scene changes suddenly from dark to light the transition does not have excessive 'ringing' (overshoot and undershoot) and that the transition happens in an acceptable amount of time, as defined in the product specification for the device under test.	Pass
Exposure Brightness	The test verified that a given camera system's luminance output (brightness level) is within the acceptable limits for each of the five available Brightness settings.	Pass
Illumination	The test verified the functional performance and light output specification.	Pass
Mechanical	The test verified the mechanical requirements for dimensions, deflection, bend radii and weight.	Pass
Camera Head Button	The test verified that when a user presses the head buttons on an attached videoendoscope the modular system correctly responds.	Pass

Biocompatibility Summary

The biocompatibility evaluation for the patient contacting components of the neuroscope was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted on the KARL STORZ Flexible Video-Neuro-Endoscope, based contact type and duration:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-11)
- Irritation (ISO 10993-11)
- Systemic Toxicity (ISO 10993-10)

The biological-toxicological safety of the patient is not affected by the materials used in the tested items.

Sterilization Validation Summary

Test	Test Method Summary	Result
STERRAD NX/100NX	SAL=10^{-6}, Half cycle method	Pass
V-PRO maX and V-PRO 60	SAL=10^{-6}, Half cycle method	Pass
STERIS SYSTEM 1E	Complete liquid chemical sterilization	Pass
100% Ethylene Oxide	SAL=10^{-6}, Half cycle method Residuals per ANSI/AAMI/ISO 109937:2008	Pass

Clinical Performance Data:	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.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, KARL STORZ Flexible Video-Neuro-Endoscope System performs as well as or better than the legally marketed predicate devices, one of which is currently marketed for the same intended use.