DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 16, 2017

Karl Storz Endoscopy-America, Inc.
Leigh Spotten
Regulatory Director
2151 E. Grand Avenue
El Segundo, California 90245

Re: K170462
Trade/Device Name: KARL STORZ ShuntScope
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: February 14, 2017
Received: February 15, 2017

Dear Leigh Spotten:

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,

Michael J. Hoffmann -S

for 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)*
K170462

Device Name
KARL STORZ ShuntScope

Indications for Use *(Describe)*
The KARL STORZ ShuntScope is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as shunt placement, tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration in pediatrics and adult population.

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 Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	May 15, 2017
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ ShuntScope 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):	Primary Predicate Device: Medtronic PS Medical's NeuroPEN Endoscope and Optical Accessories (K003914) Secondary Predicate Device: KARL STORZ Endoscopy-America's Neuro-Fiberscope (K002788) Reference Device: KARL STORZ Endoscopy-America's KSEA Sialendoscopes and Accessories (K012527)
Device Description:	The components subject of this submission are: (1) the KARL STORZ ShuntScope (Model Number: 28164SSA), (2) the examination sheath (Model Number: 11577KA) and (3) operating sheath (Model Number: 11577KE).

Intended Use:	The KARL STORZ ShuntScope is intended for visualization purposes during cranial diagnostic and therapeutic procedures.
Indications For Use:	The KARL STORZ ShuntScope is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as shunt placement, tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration in pediatrics and adult population.

Technological Characteristics:

Comparison Table: Subject vs. Primary and Secondary Predicate Devices

	Subject Device **KARL STORZ Shuntscope**	**Primary Predicate Device, K003914** **Medtronic NeuroPEN**	**Secondary Predicate Device, K002788** **KSEA Neuro-Fiberscope**	**Reference Device, K012527** **Marchal Mini Sialendoscope 0°**
Physical Characteristics				
Type of Scope	Semi-Rigid	Same as the subject device	Flexible	Same as the subject device
Insertion Shaft Diameter	1 mm (wo sheath) 1.3 mm (w 11577KA)	1.14 mm	N/A	Same as the subject device
	2.6 mm (w 11577KE)	N/A	3.7 mm	Same as the subject device
Insertion Shaft Length	161.8 mm	155 or 190 mm	340 mm	Same as the subject device
Working Channel Diameter	1.3 mm (w 11577KE)	N/A, No working channel	1.2 mm	Same as the subject device
Optical Characteristics				
Type of Imager	Fiberoptic	Same as the subject device	Same as the subject device	Same as the subject device
Direction of View	0°	Information not publicly available	Same as the subject device	Same as the subject device
Pixel Fibers	10,000	Same as the subject device	7,000	Same as the subject device
Light Source	External	Same as the subject device	Same as the subject device	Same as the subject device
Cleaning and Sterilization Methods				
Cleaning	Manual	Single-use	Same as the subject device	Same as the subject device
Sterilization	Steam	Sterile	Same as the subject device	Same as the subject device

Non-Clinical Performance Data:

Bench Testing Summary

Verification Test	**Test Method Summary**	**Result**
Surface and Edges	The surface of the ShuntScope shall be free of pores, cracks, and remainders of tooling agents.	Pass
Maximum insertion portion width	The maximum insertion portion width shall not be larger than 1 mm, stated in the instruction manual.	Pass
Field of view	The deviation of field of view shall not be greater than 15%.	Pass
Direction of view	The deviation of direction of view shall not be greater than 0° ± 10°.	Pass
Resolution	Characterization only.	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 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
Steam	SAL=10^{-6}, Half cycle method	Pass

Bibliography

The following published literature was provided to support the pediatric use of the subject device:

1. Kulkarni, Abhaya V., et al. "International Infant Hydrocephalus Study: initial results of a prospective, multicenter comparison of endoscopic third ventriculostomy (ETV) and shunt for infant hydrocephalus." Child's Nervous System 32.6 (2016): 1039-1048.
2. Depreitere, Bart, et al. "Endoscopic biopsy for intraventricular tumors in children." Journal of Neurosurgery: Pediatrics 106.5 (2007): 340-346.
3. Stone, Scellig SD, and Benjamin C. Warf. "Combined endoscopic third ventriculostomy and choroid plexus cauterization as primary treatment for infant hydrocephalus: a prospective North American series: Clinical article." Journal of Neurosurgery: Pediatrics 14.5 (2014): 439-446.
4. Zada, Gabriel, et al. "Pathogenesis and treatment of intracranial arachnoid cysts in pediatric patients younger than 2 years of age." Neurosurgical focus 22.2 (2007): 1-5.

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 ShuntScope performs as well as or better than the legally marketed predicate devices.