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

October 21, 2016

Karl Storz Endoscopy America, Inc.
Mr. Leigh Spotten
Regulatory Affairs Manager
2151 E. Grand Ave
El Segundo, CA 90245

Re: K161555
Trade/Device Name: Karl Storz Nav1 Electromagnetic Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: September 14, 2016
Received: September 15, 2016

Dear Mr. 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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*
K161555

Device Name
NAV1 electromagnetic

Indications for Use *(Describe)*
The KARL STORZ NAV1 electromagnetic navigation system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures under visual control. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to radiological image data or digitized landmarks of the anatomy

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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7. 510(k) Summary

Traditional Premarket Notification Submission (510(k)) Summary
Prepared in accordance with 21 CFR 807.92

7.1 Submitter Information

Sponsor name:	KARL STORZ Endoscopy America, Inc.
Sponsor address:	2151 E. Grand Ave. El Segundo, CA 90245 USA
Sponsor telephone:	424-218-8100
Sponsor fax:	424-218-8519
Establishment Registration:	3010202439
Contact person:	Leigh Spotten
Contact title:	Director, Regulatory Affairs
Email direct:	leigh.spotten@karlstorz.com
Telephone direct:	424-218-8738
Date summary prepared:	Oct. 21, 2016

7.2 Device Name

Trade (proprietary):	NAV1 electromagnetic
Common (usual):	Stereotaxic Instrument
Classification:	21 CFR 882.4560 (Class II)
FDA Product Code:	PGW
Review Panel:	Ear Nose & Throat

7.3 Substantially Equivalent Predicate Device

FIAGON Navigation System, K133573
KARL STORZ Navigation Panel Unit , K122096

7.4 Device Description

The NAV1 Electromagnetic is an intraoperative image guided localization system that links a navigated instrument tracked by an electromagnetical sensor to a virtual computer image space on a patient's preoperative diagnostic image data set (CT or MRI). The system is intended to be used as a positioning aid for navigation in ENT stereotactic surgery, including but not limited to the endoscopic surgery. The NAV1 Electromagnetic is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure can be identified relative to the radiological imaging-based model of the anatomy (CT or MRI). Surgical procedures include but are not limited to the following: maxillary antrostomies, ethmoidectomies, sphenoidectomies, sphenoid explorations, turbinate resections, extensive sino-nasal polyposis, frontal sinusotomies, intranasal procedures, intranasal tumor resections, otologic surgery, and extracranial skull base diseases.
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7.5 Intended Use

The KARL STORZ NAV1 electromagnetic navigation system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures under visual control. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure in the field of ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to radiological image data or digitized landmarks of the anatomy.

7.6 Technological Characteristics

The NAV1 electromagnetic navigation system and the predicate FIAGON Navigation System both include hardware and software that enable real-time surgical navigation, mapping points between the patient's anatomy and corresponding points on radiologic images of the patient. Both systems employ instruments to continuously update the instrument position on images by electromagnetic tracking. The performance of the subject device has undergone system verification and validation testing to ensure it does not introduce new issues of safety or effectiveness.

7.7 Performance Characteristics

Nonclinical performance characteristics evaluated in support of the substantial equivalence of the NAV1 electromagnetic navigation system include system verification and validation testing. The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the patient contacting components of the system (reusable EM Navigated instruments, single-use headband and single-use patient tracker adhesive pad) was performed according to ISO 10993-1and FDA Guidance.
The following tests were conducted, based on contact type and duration:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity

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

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the KARL STORZ NAV1 electromagnetic navigation system, consisting of the NAV1 Module, the NAV1 electromagnetic Module and EM Navigated instruments. The system complies with the IEC 60601-1 standards for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device

was considered as a “moderate” level of concern because a software malfunction could lead to a delay in diagnosis.

Bench testing

The performance of the NAV1 Electromagnetic system (40820001) has undergone verification and validation testing to ensure it does not introduce new issues of safety or effectiveness, and to demonstrate that the final design has met all of its requirements. Performance testing reports are provided in the Performance Testing (Bench) of this 510(k). The following tests were conducted:

- Evaluation of the accuracy of electromagnetically tracked instruments (before and after Reprocessing)
- Evaluation of time accuracy of the ENT Navigation Software
- User acceptance testing.

7.8 Cleaning and Sterilization

Reusable EM Navigated instruments (i.e. Patient Tracker, Probes, Curettes, and Suction Tubes) are delivered non-sterile; they must be cleaned and sterilized prior to the initial use and before each subsequent use. Compatible headband and patient tracker adhesive pad are single-use products and must be disposed of after patient use. Sterility efficacy demonstrated a sterility assurance level of 10^{-6} in a pre-vacuum steam sterilizer, STERRAD® 100NX® Standard sterilization cycle, and V-PRO® 1 Plus Lumen sterilization cycle. Manual cleaning effectiveness was demonstrated with sufficient recovery efficiency for residual protein and residual hemoglobin.

7.9 Animal and Clinical Performance Data:

Animal and Clinical performance data are not required to demonstrate substantial equivalence for this type of device.

7.10 Conclusion

Based on the information provided in this premarket notification, KARL STORZ concludes that the NAV1 electromagnetic navigation system is safe, effective, and substantially equivalent to the predicate FIAGON Navigation System in its indication for use, device design, materials, performance characteristics, and operational principles.