DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 14, 2017

Fiagon Gmbh
% Yarmela Pavlovic
Regulatory Counsel
Hogan Lovells US LLP
3 Embarcadero Center, Suite 1500
San Francisco, California 94111

Re: K163209
Trade/Device Name: Fiagon Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: August 15, 2017
Received: August 15, 2017

Dear Ms. Pavlovic:

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)*
K163209

Device Name
Fiagon Navigation System

Indications for Use *(Describe)*
The Fiagon Navigation System is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. The Fiagon Navigation System 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 cranial surgery can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:
- Craniotomies/Craniectomies (e.g., Tumor Resection)
- Skull Base Procedures
- Cranial Biopsies
- General Catheter Shunt Placement
- Pediatric Catheter Shunt Placement

The user should consult the "Bench Accuracy" section of the User Manual to assess whether the accuracy of the system is suitable for their needs.

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

510(k) Summary
Fiagon Navigation System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter: Fiagon GmbH
Address: Neuendorfstrasse 23b
16761 Hennigsdorf, Germany

Telephone: +49 3302 201 21 10
Telefax: +49 3302 201 21 15

Contact: Dr. Dirk Mucha, CTO

Date Prepared: 2017-9-11

Name of Device and Name/Address of Sponsor

Trade Name: Fiagon Navigation System
Common Name: Image guided surgery system
Classification: Class II per 21 CFR 882.4560
Device: Stereotaxic Instrument
Product Code: HAW

Predicate Devices

- Fiagon Navigation System, Fiagon GmbH (K151156 – Primary Predicate)
- StealthStation System with Synergy Cranial Software, Medtronic Navigation, Inc. (K150216) and Skull Mounted Patient Tracker (K141833)

Intended Use / Indications for Use

The Fiagon Navigation System is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. The Fiagon Navigation System 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 cranial surgery can be identified relative to a CT or MR based model of the anatomy.

Example procedures include, but are not limited to:

Cranial Procedures:

- Craniotomies/Craniectomies (e.g., Tumor Resection)
- Skull Base Procedures
- Cranial Biopsies
- General Catheter Shunt Placement
- Pediatric Catheter Shunt Placement

The user should consult the "Bench Accuracy" part of the User Manual to assess if the accuracy of the system is suitable for their needs.

Device Description

The Fiagon Navigation System displays the position of the instruments in preoperative scans (e.g., CT, MRI, fluoroscopy) utilizing electromagnetic tracking technology. The position of the instrument with integrated sensor and the patient equipped with localizers are localized within an electromagnetic field generated by a field generator. The principle of navigation is based on electromagnetic spatial measuring of localizer element in a generated electromagnetic field.

The display of navigation information requires an image-to-patient registration procedure. During registration procedure, the navigation system determines the coordinate transformation between the intraoperative position of the patient and the position of the preoperative scan by fiducial marker, anatomical landmark or surface matching. Thereafter, the spatial position of the instrument is displayed superimposed to the image data. The navigation information is updated with a rate of 15 to 45 Hz.

The components of the navigation system are

1. Navigation unit with Navigation software. It has interfaces for screen, mouse and the components 2 – 4 below.

2. Navigation sensor (Headrest with field generator)

3. Navigation instrument (ShuntPointer, BiopsyPointer190 and BiopsyPointer 250)

4. Patient reference localizer (Localizer Set Bone Anchor and Localizer Adhesive Pad)

The navigation unit is connected to a medical monitor. The unit runs the navigation software. Preoperative radiological images of the patient (DICOM CT, CBCT, MR) are imported to the system by means of CD-ROM, USB storage media or LAN network and displayed in appropriate way defined by the software.

The navigation unit includes the spatial measuring device electronics as well. This has connections to the field generating device (navigation sensor), the patient localizer and the navigation instrument.

The patient reference localizer and navigation instrument are tracked within the generated field by localizer elements integrated in the devices.

The patient reference localizer is fixed to the patient's anatomy and references it, while the instrument is tracked in relation to the patient localizer and thus to the patient's anatomy.

The components and accessories of the system are listed in the table below:

Components	**Grouping**	**Material used (if body contact)**	**Property**	**Previously cleared in**
Navigation Unit	Unit	n.a.	OR Equipment Rating: 110 - 240Vac 50-60 Hz, 200VA	Cleared in K151156/K133573
BiopsyPointer 190	Instrument	Stainless steel medical grade adhesive	reusable, 10 times	Cleared in K151156
BiopsyPointer 250	Instrument	Stainless steel medical grade adhesive	reusable, 10 times	Cleared in K151156
ShuntPointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times	Cleared in K151156
Localizer Set Bone Anchor	Patient reference localizer	n.a.	reusable	Part of this submission
Localizer Adhesive Pad	Patient reference localizer	n.a.	reusable	Cleared in K151156/K133573

Comparison of Technology Characteristics

The Fiagon Navigation System has the same intended use and similar indications for use as the predicate devices. Specifically, the intended use of the Fiagon Navigation System is identical to the predicate devices, which is use in locating anatomical structures in either open or percutaneous neurosurgical procedures. Although the modified device features an additional indication (pediatric shunt placement) compared to the predicate Fiagon device, that indication is also included in the StealthStation predicate (K150216). The device remains technologically unchanged compared to the Fiagon device cleared in K151156 with the single exception of the addition of a pinless fixation method for the localizer, which is similar to Medtronic's skull mounted patient tracker predicate (K141833) used with the predicate StealthStation. The minor differences in technological characteristics do not raise any different questions of safety or effectiveness. All three devices use electromagnetic tracking technology, and utilize anatomical or fiducial reference points on the patient's anatomy for intraoperative registration to the image-based model of the anatomy. Performance data demonstrate that the Fiagon navigation system performs in a manner that is substantially equivalent to the predicate devices. In addition, sterilization, electrical safety/EMC and biocompatibility testing has been conducted to further support the device performance.

Therefore, the device is substantially equivalent to its predicates.

Comparison of Fiagon Navigation System to the predicate devices

Property	**Fiagon Navigation System**	**Fiagon Navigation System**	**StealthStation System with Synergy Cranial Software**
510(k) No.	Subject Device	K151156	K150216, K141833
Indications for use	The Fiagon Navigation System is intended as an aid for locating anatomical structures in either open or percutaneous neurosurgical procedures. The Fiagon Navigation System 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 cranial surgery can be identified relative to a CT or MR based model of the anatomy. Example procedures include, but are not limited to: Cranial Procedures: - Craniotomies/Craniectomies (Eg: Tumor resection) - Skull Base Procedures - Cranial Biopsies - General Catheter Shunt Placement - Pediatric Catheter Shunt Placement	The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures. The Fiagon Navigation System 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 cranial surgery can be identified relative to a CT or MR based model of the anatomy. Example procedures include, but are not limited to: Cranial Procedures: - Craniotomies/Craniectomies (Eg: Tumor resection) - Skull Base Procedures - Cranial Biopsies - General Catheter Shunt Placement	The StealthStation System, with Synergy® Cranial software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical procedures. The system is indicated for any medical condition in which reference to a rigid anatomical structure can be identified relative to images of the anatomy. This can include, - Cranial Biopsies - Tumor Resections - Craniotomies/Craniectomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/Pallidotomies - Pituitary Tumor Removal - CSF Leak Repair - Pediatric Catheter Shunt Placement - General Catheter Shunt Placement
Reference images	CT/ MR/ Cone Beam CT	CT/ MR/ Cone Beam CT	CT/X-Ray based, MR based Nuclear Medicine based
Tracking method	Electromagnetic	Electromagnetic	Optical (infra-red) Electromagnetic Either of the technologies can be selected
Field generator	Integrated into headrest or bedside mounted, Head clamp mounted	Integrated into headrest or bedside mounted, Head clamp mounted	Electromagnetic tracking system can be used from its discreet location on a StealthStation System or attached to the OR bedrail
Method of registration	Surface matching Fiducial matching	Surface matching Fiducial matching	Surface matching Fiducial matching
Instrument verification	Instrument verified after registering of patient. User needs to confirm on	Instrument verified after registering of patient. User needs to confirm on	Instrument is verified after registering to the system. User needs to confirm on

Property	Fiagon Navigation System	Fiagon Navigation System	StealthStation System with Synergy Cranial Software
	anatomical landmark. Same needs to be done after an interval of time.	anatomical landmark. Same needs to be done after an interval of time.	anatomical landmark.
Tracker Location	Rigid instruments: handle instruments: tip	Rigid instruments: handle Flexible instruments: tip	Rigid instruments: handle Flexible instruments: tip
Mean bench accuracy .	Position Mean: < 2mm Angular: Mean: < 2°	Position Mean: < 2mm Angular: Mean: < 2°	Position Mean: < 2mm Angular: Mean: < 2°
Field distortion detecting mechanism	Yes. Field distortions are detected by redundant localizer information and distorted values are excluded from displaying	Yes. Field distortions are detected by redundant localizer information and distorted values are excluded from displaying	Yes Algorithms monitor the disturbances in electromagnetic field.
Navigation Instruments	Pointing Probes, Stylet, patient tracker (non-invasive and Skull mounted)	Pointing Probes, Stylet, patient tracker (non-invasive)	Navigation pointer and pointing probes Patient tracker (non-invasive and skull mounted)
Safety and EMC	Meets AAMI/ANSI ES 60601-1:2005 IEC 60601-1-2:2007	Meets AAMI/ANSI ES 60601-1:2005 IEC 60601-1-2:2007	Meets IEC standards e.g., IEC 60601-1 for medical equipment UL60601-1
Sterilization	Reusable, validated cleaning and sterilization procedure	Reusable, validated cleaning and sterilization procedure	Reusable, validated cleaning and sterilization procedure

Performance Testing

Bench testing was conducted to determine the device accuracy of the Fiagon Navigation System with Localizer Set Bone Anchor as the fixation method in neurosurgical procedures when using three instruments (BiopsyPointer 190, BiopsyPointer 250, and the ShuntPointer). The assessments included measuring the registration and application error related to the trajectory (from the entry point down to the final target) by comparing preoperative surgical planning for instrument insertion with the actual instrument location in the postoperative images.

The measurement phantom was a model of the human skull with half cranium and an imbedded structure that mimics part of the brain. Rods with a touch point and tubes were placed in this structure to facilitate the measurement of the trajectory of the surgical tube and the target registration measurements. The phantom was scanned with computer tomography (CT) prior to the testing. The axial CT slices had a resolution of 0.45 mm x 0.45 mm (512 x 512 pixels) in each layer and 0.75 mm layer distance. The positions of the reference points were measured using a Coordinate Measurement Machine (CMM) with an accuracy of 0.018 mm. The coordinate system of the CMM was then registered with the coordinate system of the CT images.

During the course of the evaluation, the Localizer Set Bone Anchor is attached to the phantom head in a similar fashion as the real patient treatment scenario. Each rod is touched at the corresponding approach path with the navigation point of the instrument, which was guided in alignment to the planned interventional trajectory until the target point was reached. The position and orientation of the pointer in the coordinate system of the previously registered images were then recorded.

The results showed that the average Target Registration Error (TRE) for the device with Localizer Set Bone Anchor was 1.17 mm (99% CI upper bound: 2.47 mm) and the average Angular Registration Error (ARE) was 1.45° (99% CI upper bound: 2.8°), which were similar to the accuracy of the predicate devices.

Similar testing was conducted for the Localizer Adhesive Pads. The results showed that the average Target Registration Error (TRE) for the device with Localizer Adhesive Pads was 1.42 mm (99% CI upper bound: 2.42 mm) and the average Angular Registration Error (ARE) was 1.46° (99% CI upper bound: 2.9°), which were also similar to the accuracy of the predicate devices.

Therefore, the non-clinical data demonstrate that the device performs comparably to the predicates device for the same intended use.

In addition, the Localizer Set Bone Anchor was subjected to biocompatibility assessments for cytotoxicity, irritation, sensitization, and acute systemic toxicity, and material mediated pyrogenicity. The testing results showed that the Localizer Set Bone Anchor is biocompatible.

Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the Fiagon Navigation System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any different issues of safety or effectiveness. The results from the bench testing demonstrate that the device performs similarly to the predicate devices.