



Food and Drug Administration
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April 1, 2016

Fiagon GmbH
Dr. Dirk Mucha
Manager Regulatory Affairs
Neuendorfstrasse 23b
Hennigsdorf, Germany 16761

Re: K151156
Trade/Device Name: Fiagon Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: HAW
Dated: February 25, 2016
Received: March 02, 2016

Dear Dr. Mucha:

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" (21CFR 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

Indications for Use

510(k) Number (if known)

K151156

Device Name

Fiagon Navigation System

Indications for Use (Describe)

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

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

Fiagon Navigation System

1. Submitter Information

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Contact: Dr. Dirk Mucha, Manager Regulatory Affairs
Date Prepared 2016-02-24

2. Device Information

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

3. Purpose of Submission

The purpose of this submission is to gain clearance for a new Image Guided Surgery System.

4. Predicate Device Information

The Fiagon Navigation System described in this submission is substantially equivalent to the following predicates:

	Predicate Device	Manufacturer	510(k) No.
1. Primary predicate	Stealth station system with synergy cranial Software	Medtronic navigation, Inc	K150216
2.	BrightMatter Navigation System V1.0	Synaptive Medical Inc.	K142024

Device Description

The Fiagon Navigation System displays the position instruments in preoperative scans (e.g., CT, MRI, fluoroscopy) utilizing electromagnetic tracking technology. For cranial procedures, the use of this device is restricted to rigid fixation with a patient reference localizer attached directly to the skull clamp. The position of the instrument with integrated sensor and the patient referencing localizer (attached to the skull clamp) 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 device Fiagon Navigation System utilizing similar technology than the proposed device has been previously cleared for a different intended use. This device is listed as a reference device.

	Reference Device	Manufacturer	510(k) No.
R1.	Fiagon Navigation System Similar device, cleared for different intended use	Fiagon GmbH	K133573

Device Design

The components of the navigation system are

1. Navigation unit with Navigation software. It has interfaces for screen, mouse and the components 2 - 4.
2. Navigation sensor (Headrest with field generator)
3. Navigation instrument
4. Patient reference localizer (with fixation of the localizer on the skull clamp using the 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) is 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 compromises the spatial measuring device electronics as well. This has connections to the field generating device (navigation sensor), the patient reference localizer and the navigation instrument.

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 skull clamp and references the patient's anatomy, while the instrument is tracked in relation to the patient reference localizer and thus to the patient's anatomy.

List of components/accessories

Components	Grouping	Material used (if body contact)	Property
Navigation Unit	Unit	n.a.	OR Equipment Rating: 100 -240Vac 50-60 Hz, 200VA
Navigation Headrest Flat	Navigation Sensor	n.a.	OR Equipment
Navigation Headrest Maquet	Navigation Sensor	n.a.	OR Equipment
Navigation Headrest Universal	Navigation Sensor	n.a.	OR Equipment
FlexPointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
FlexPointer 1.5	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
FinePointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
BiopsyPointer 190	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
BiopsyPointer 250	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
ShuntPointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
RegistrationPointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
Localizer Adhesive Pad	Patient reference localizer	n.a.	reusable
Adhesive Pad	Fixation material	medical grade adhesive tape	single use

5. Intended Use

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

6. Comparison of Technological Characteristics

The substantial equivalence of the Fiagon Navigation System to the predicates is shown by similarity in intended use, indications for use, materials, and performance. The Fiagon Navigation System and its predicates and the reference device utilize:

- Electromagnetic tracking technology for navigation in 2 cases and optical tracking in 1 case. (For further details refer to the table below).
- Anatomical or fiducial reference points on the patient's anatomy for intraoperative registration to the image-based model of the anatomy in 2 cases (Fiagon Navigation System and Stealth station system with synergy cranial Software) and Fiducial matching in the case of BrightMatter Navigation System V1.0).
- CT or MR image sets as reference images for the image-based model

The primary difference between the Fiagon Navigation System and its two predicates is that the Fiagon System includes the option of navigating flexible-tip instruments by having the instrument localizer in the tip of the instrument. Since tracking a localizer in the tip of the instrument provides similar navigation accuracy as tracking the tip of a rigid instrument via a localizer mounted to the instrument handle, this difference does not raise new issues of safety and effectiveness.

Comparison of Fiagon Navigation System to the predicate and reference devices

Property	Fiagon Navigation System	Predicate 1 Stealth station system with synergy cranial Software	Predicate 2 BrightMatter Navigation System V1.0	Reference device Fiagon Navigation System
510(k) No.	Subject of investigation	K150216	K142024	K133573
Reference images	CT/ MR/ Cone Beam CT	CT/X-Ray based, MR based Nuclear Medicine based	MRI Images and DTI images of the brain	CT/ MR/ Cone Beam CT

Property	Fiagon Navigation System	Predicate 1 Stealth station system with synergy cranial Software	Predicate 2 BrightMatter Navigation System V1.0	Reference device Fiagon Navigation System
Tracking method	Electromagnetic	Optical (infra-red) Electromagnetic Either of the technologies can be selected	Optical tracking	Electromagnetic
Field generator	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	Optical Tracking Technology. The surgical display and tracking camera are mounted on an Auxiliary Cart. The computer is housed in a Navigation Cart.	Integrated into headrest
Method of registration	Surface matching Fiducial matching	Surface matching Fiducial matching	Fiducial matching The system works with 3D cameras that know the exact location and orientation of the tools being used. It overlays the location of the tools over the 3D visualizations of the brain and uses the BrightMatter Plan system to develop a path for the instruments to take.	Surface matching Fiducial matching
Instrument verification	Instrument verified after registering of patient. User needs to confirm on anatomical landmark. Same needs to be done after an interval of time.	Instrument is verified after registering to the system. User needs to confirm on anatomical landmark.	Instrument is verified after registering to the system. User needs to confirm on anatomical landmark.	Instrument verified after registering of patient. User needs to confirm on anatomical landmark. Same needs to be done after an interval of time.
Tracker Location	Rigid instruments: handle Flexible instruments: tip	Rigid instruments: handle Flexible instruments: tip	Tip Tracking possible after calibrating the device to the navigation system.	Rigid instruments: handle Flexible instruments: tip
Mean bench accuracy as Target Registration Error (TRE) and Angular registration error.	Position Mean: < 2mm Angular: Mean < 2°	The System has demonstrated accuracy with a mean positional error of 2mm and mean trajectory error of 2 degrees.	Mean positional error was measured to be less than 2 mm and mean angular error was measured to be less than 2 degrees	Mean: 0.93- 1.2 mm STD: 0.35 – 0.44 mm No angular values given

Property	Fiagon Navigation System	Predicate 1 Stealth station system with synergy cranial Software	Predicate 2 BrightMatter Navigation System V1.0	Reference device Fiagon Navigation System
Field distortion detecting mechanism	Yes. Field distortions are detected by redundant localizer information and distorted values are excluded from displaying	Yes Algorithms monitor the disturbances in electromagnetic field.	Not applicable as it uses optical technology	Yes. Field distortions are detected by redundant localizer information and distorted values are excluded from displaying
Navigation Instruments	<ul style="list-style-type: none"> Pointing Probes 	<ul style="list-style-type: none"> Navigation pointer and pointing probes 	<ul style="list-style-type: none"> Pointing probes 	<ul style="list-style-type: none"> Pointing Probes
Instrument Materials	Instruments with body contact are from stainless steel	Unknown	Unknown	Instruments with body contact are from stainless steel
Safety and EMC	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	unknown	Meets IEC 60601-1 2nd ed and 3rd ed. EN 60601-1-2:2007
Indications for use	<p>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 can be identified relative to a CT or MR based model of the anatomy.</p> <p>Example procedures include, but are not limited to:</p> <p>Cranial Procedures:</p> <ul style="list-style-type: none"> Skull base procedures, 	<p>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.</p> <p>This can include,</p> <ul style="list-style-type: none"> Cranial Biopsies Tumor Resections - Craniotomies/Cranie ctomies - Skull Base Procedures - Transsphenoidal Procedures - Thalamotomies/ Pallidotomies - 	<p>BrightMatter Navigation System is intended as a planning and intraoperative guidance system to enable open and percutaneous computer assisted surgery. The system is indicated for medical conditions requiring neurosurgical cranial procedures where the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The system should be operated only by trained personnel such as surgeons and other clinic staff.</p>	<p>The Fiagon Navigation System is intended as an aid for precisely locating anatomical structures in either open or percutaneous 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 ENT surgery, such as the paranasal sinuses, mastoid anatomy, can be identified relative to a CT or MR based model of the anatomy.</p>

Property	Fiagon Navigation System	Predicate 1 Stealth station system with synergy cranial Software	Predicate 2 BrightMatter Navigation System V1.0	Reference device Fiagon Navigation System
	<ul style="list-style-type: none"> - Craniotomies/Craniectomies(e.g. Tumor resections), - Cranial biopsies, - General catheter Shunt placement 	<ul style="list-style-type: none"> Pituitary Tumor Removal - CSF Leak Repair - Pediatric Catheter Shunt Placement - General Catheter Shunt Placement 		

7. Performance Data

Testing was performed in order to determine device precision and accuracy and the electromagnetic field distortion detection mechanism. The following nonclinical tests were performed to determine substantial equivalence:

Bench testing was conducted to determine the device accuracy and the performance of the electromagnetic field distortion mechanism.

The tests performed to validate the accuracy of our navigation instruments ranged from validation of required accuracy (Positional accuracy and angular accuracy with registration) to measurement of technical accuracy with co-ordinate measurement system followed by measurement of positional and angular accuracy without registration to measure the angular accuracy of the instrument itself.

The non-clinical data support the safety of the device demonstrate that the Fiagon Navigation System perform as intended in the specified use conditions. The non-clinical data demonstrate that the device performs comparably to the predicate device for the same intended use.

8. Conclusion

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 new issues of safety or effectiveness.