

APR 30 2014

K133573

510(k) Summary Fiagon Navigation System

1. Submitter Information

Submitter: Fiagon GmbH
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Contact: Mr. Dirk Mucha, Manager Regulatory Affairs
Date Prepared: 2013-11-15 (original), 2014-03-26 (revision)

2. Device Information

Trade Name: Fiagon Navigation System
Common Name: Image guided surgery system
Classification: Class II per 21 CFR 882.4560
Device: Ear, Nose, and Throat Stereotaxic Instrument
Product Code: PGW

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	StealthStation® System GoldenEye™ Micro Magnetic Tracking System	Medtronic Surgical Navigation Technologies	K001284
2	InstaTrak® (InstaTrak®3000)	Visualization Technology, Inc.	K960330 (K983529)
3	Regulus™ Navigator	COMPASS International Inc.	K964229

5. Device Description

The Fiagon Navigation System displays the position 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.

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 material)

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 comprises as well the spatial measuring device electronics. This has connections to the field generating device (navigation sensor), the patient 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 patients anatomy and references it, while the instrument is tracked in relation to the patient 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: 110 -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
FinePointer	Instrument	Stainless steel medical grade adhesive	reusable, 10 times
Localizer Headband	Patient reference localizer	n.a.	reusable
Localizer Adhesive Pad	Patient reference localizer	n.a.	reusable
Headband	Fixation material	medical grade adhesive tape	single use
Adhesive Pad	Fixation material	medical grade adhesive tape	single use

6. Intended Use

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.

Example procedures include, but are not limited to:

ENT Procedures;

Transphenoidal access procedures.

Intranasal procedures.

Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies,

Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.

ENT related anterior skull base procedures

7. 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 utilize:

- Electromagnetic tracking technology for navigation
- Anatomical or fiducial reference points on the patient's anatomy for intraoperative registration to the image-based model of the anatomy
- CT or MR image sets as reference images for the image-based model

The primary difference between the Fiagon Navigation System and its predicates is that the Fiagon System includes the option of navigating flexible-tip instruments by mounting 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.

8. 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.

A mean bench accuracy of 0.9 mm (Standard deviation 0.34 mm) was measured which compares to the values 0.8 mm to 1.0 mm reported for the predicate devices.

Results showed that the device detected field distortions under normal conditions before the induced error became larger than 0.9 mm which compares to a value of 1.0 mm reported for the predicate device.

Reported mean clinical accuracy was 1.79 mm (Standard deviation 0.4 mm) which compares to the reported mean clinical accuracy of the predicate devices in the range of 1.64 mm to 2.8 mm.

The results supports the claim of substantial equivalence to the predicate devices.

9. 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.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 30, 2014

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

Re: K133573
Trade/Device Name: Fiagon Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: April 2, 2014
Received: April 2, 2014

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" (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

Indications for Use Statement

510(k) Number: K133573

Device Name: Fiagon Navigation System

Indications for Use:

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ENT related anterior skull base procedures

Prescription Use X
(Part 21 CFR 801 Subpart D)

And / Or

Over-The-Counter-Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sageev George -S

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