DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 1, 2016

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

Re: K162176
Trade/Device Name: Fiagon Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: November 1, 2016
Received: November 1, 2016

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 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 on last page

510(k) Number *(if known)*

K162176

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 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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SECTION 6 – 510(k) Summary

August 3, 2016

1. Submitter Information/ 510(k) Holder

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

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

Contact: Mr. Dirk Mucha, CTO

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 modified version of the previously cleared Fiagon Navigation System (K133573).

4. Predicate Device Information

Fiagon Navigation System (K133573)

5. Device Description

The Fiagon Navigation System displays 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.

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 device is a modified version of the previously cleared Fiagon Navigation System (K133573). The reason for this Special 510(k) is to describe the addition of WiFi connectivity to the navigation system and the addition of an iPad remote control with automatic registration feature. The changes do not raise new types of safety or effectiveness questions. Bench testing has been conducted to evaluate the modified system, and results confirm that the device performs as intended and in a similar manner compared to the predicate.

8. Performance Data

The following nonclinical performance testing was conducted to support the substantial equivalence of the device to the predicate.

- Positioning accuracy test for target registration
- Wireless coexisting testing
- Software testing

In all instances, the device functioned as intended and similar to the predicate, supporting the substantial equivalence to the predicate device.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicate, the Fiagon Navigation System has been shown to be substantially equivalent to the cleared predicate and the modified device does not present any new issues of safety or effectiveness.