DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 16, 2017

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

Re: K163416
Trade/Device Name: Fiagon Navigation - Pointertube Straight And Pointertube Keat
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: January 18, 2017
Received: January 18, 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 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)*

K163416

Device Name
Fiagon Navigation – PointerTube Straight and PointerTube Keat

Indications for Use *(Describe)*
Indications for Use (Describe)

The Fiagon Navigation – PointerTube Straight and the PointerTube Keat are intended as aids for precisely locating anatomical structures in either open or percutaneous procedures. They are indicated for use with the Fiagon Navigation system using electromagnetic navigation.

The instruments are 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.
Skull base procedures for ENT access

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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SECTION 5 – 510(K) SUMMARY

510(k) Summary

December 5, 2016

1. Submitter Information/ 510(k) Holder

Submitter: Fiagon GmbH
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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 – PointerTube Straight and PointerTube Keat
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 modified versions of two previously cleared instruments, Fiagon Navigation – PointerTube Straight (K141456) and PointerTube Sinus Frontalis (K141456). The modified version of the PointerTube Straight has modified olive leaf-shaped tip with a different inner and outer diameter. The tube length remains identical in this case. The Sinus Frontalis has been modified in instrument length as well as diameter to a new instrument - the PointerTube Keat.

4. Predicate Device Information

Fiagon Navigation – PointerTube Straight (K141456) and PointerTube Sinus Frontalis (K141456)

5. Device Description

The Fiagon Navigation – PointerTube Straight and the PointerTube Keat are 10 time use instruments intended to be used with the Fiagon Navigation system.

Each device incorporates a sensor, which is tracked by the navigation system within the low-energy magnetic field of a field generator (part of the navigation system).
The navigation software (part of the navigation system) displays the position of the instruments in preoperative scans (e.g., CT, MRI, fluoroscopy).

6. Intended Use

The Fiagon Navigation – PointerTube Straight and the PointerTube Keat are intended as aids for precisely locating anatomical structures in either open or percutaneous procedures. They are indicated for use with the Fiagon Navigation system using electromagnetic navigation.

The instruments are 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.
Skull base procedures for ENT access

7. Comparison of Technological Characteristics

The PointerTube Straight and the PointerTube Keat are modified versions of previously cleared PointerTube Straight (K141456) and PointerTube Sinus Frontalis (K141456) respectively. The reason for this Special 510(k) is to describe changes in the diameter and shape of the tip for the PointerTube Straight and change of diameter, length and tip for the PointerTube Keat. These changes do not raise new issues of safety and effectiveness of the instruments.

8. Performance Data

Testing was performed in order to confirm continued precision and accuracy of the modified devices. Testing was also completed to ensure functionality and compatibility with the Fiagon Navigation system, as well as to confirm that the change in design of the modified instrument does not alter the performance characteristics of the device.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the PointerTube Straight and the PointerTube Keat have been shown to be substantially equivalent to the predicate PointerTube Straight and the PointerTube Sinus Frontalis, respectively, and do not present any new issues of safety or effectiveness.