DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 8, 2014

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

Re: K141456
Trade/Device Name: Fiagon Navigation – Extended Instrument Set ENT
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: September 5, 2014
Received: September 10, 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" (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,

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

510(k) Number (if known): K141456

Device Name: Fiagon Navigation – Extended Instrument Set ENT

Indications for Use:

The Fiagon Navigation – Extended Instrument Set ENT is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is indicated for use with the Fiagon Navigation system using electromagnetic navigation.
The Fiagon Navigation – Extended Instrument Set ENT 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.
Skull base procedures for ENT access

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)

510(k) Summary

May 28, 2014

1. Submitter Information

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, Manager Regulatory Affairs

2. Device Information

Trade Name: Fiagon Navigation – Extended Instrument Set ENT
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 set of instruments for the Image Guided Surgery System, Fiagon Navigation system (K133573).

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	Fiagon Navigation System	Fiagon GmbH	K133573
2	Malleable Suction™ Instruments	Medtronic Navigation, Inc.	K133665
3	Instatrak®	Visualization Technology, Inc.	K960330

5. Device Description

The Fiagon Navigation - Extended Instrument Set ENT are reusable instruments intended to be used with the Fiagon Navigation system. The instruments in the Set are electromagnetically navigated devices that are

a. Navigated suction instruments (malleable, designed to be bendable by hand, sensor within the tip, attachable to standard surgical vacuum suction systems)

b. Navigated pointing devices (flexible, sensor within the tip)

c. Registration probe (designed for non.sterile patient registration)

d. Instrument adaptors (designed for mechanical connection to cylindric schaped surgical instruments of different diameters)

Each device incorporates a sensor device which is tracked by the navigation system with in 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)

List of components

Components	**Grouping**	**Sterility State**	**Patient contact**
FlexTube 3 mm	Suction and navigation Instrument	• user sterilized, • reusable, • delivered in non steril state	• limited duration (< 24h) • External communicating • Tissue/bone/dentin
FlexTube 4 mm	Suction and navigation Instrument	• user sterilized, • reusable, • delivered in non steril state	• limited duration (< 24h) • External communicating • Tissue/bone/dentin
PointerTube Straight	Suction and navigation Instrument	• user sterilized, • reusable • delivered in non steril state	• limited duration • External communicating • Tissue/bone/dentin
PointerTube Stammberger	Suction and navigation Instrument	• user sterilized, • reusable • delivered in non steril state	• limited duration • External communicating • Tissue/bone/dentin
PointerTube Sinus Frontalis	Suction and navigation Instrument	• user sterilized, • reusable • delivered in non steril state	• limited duration • External communicating • Tissue/bone/dentin
RegistrationPointer	Pointing Instrument for patient registration only, ball tip	• reusable • not to be sterilized • outside sterile field	• limited duration • Surface communicating • Skin

Components	Grouping	Sterility State	Patient contact
VenteraPointer	Pointing Instrument	• user sterilized, • reusable, • delivered in non steril state	• limited duration (< 24h) • External communicating • Tissue/bone/dentin
GuideWire	Pointing Instrument	• user sterilized, • reusable, • delivered in non steril state	• limited duration (< 24h) • External communicating • Tissue/bone/dentin
PointerShell 4 mm	Instrument adapter	• user sterilized, • reusable, • delivered in non steril state	• limited duration • Surface communicating • Skin
PointerShell 5 mm	Instrument adapter	• user sterilized, • reusable, • delivered in non steril state	• limited duration • Surface communicating • Skin
PointerShell 3 mm	Instrument adapter	• user sterilized, • reusable, • delivered in non steril state	• limited duration • Surface communicating • Skin

6. Intended Use

The Fiagon Navigation - Extended Instrument Set ENT is intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. It is indicated for use with the Fiagon Navigation system using electromagnetic navigation.
The Fiagon Navigation – Extended Instrument Set ENT 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 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 substantial equivalence of the Fiagon Navigation – Extended Instrument Set ENT 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 attached or included in surgical instruments (all predicates)
- Malleable suction instruments enabled for image guidance (Predicate 2)
- Adapters for Instruments for enabling image guidance (Predicate 3)
- Instruments with tracking sensor at the instrument tip, precalibrated (Predicate 1 and 2)

The primary difference between the Fiagon Navigation – Extended Instrument Set ENT and it predicates Fiagon Navigation System is that the Fiagon Navigation – Extended Instrument Set ENT provides electromagnetic tracking of the same kind in instruments of different geometry. This different does not raise new issues of safety and effectiveness, with respect to the following:

Cannulated instruments have been demonstrated by predicate 2. Therefore, the suction instruments of the Extended Instrument Set ENT do not raise new issues of safety and effectiveness.

Instrument adapters have been demonstrated by predicate 3. Therefore, the instrument adapters of the Extended Instrument Set ENT do not raise new issues of safety and effectiveness

8. Performance Data

Testing was performed in order to determine device precision and accuracy. 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 0.7 mm – 1.2 mm (Standard deviation 0.29 mm – 0.42 mm) was measured for the different instrunents. All 95% confidence levels were < 2mm which compares to the values 0.9 mm (mean) resp. <3 mm (95% confidence) reported for the predicate devices.

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

Testing was completed to ensure functionality and compatibility with the Fiagon Navigation system.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the Fiagon Navigation – Extended Instrument Set ENT 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.