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

March 23, 2016

Fiagon Gmbh
Dr. Dirk Mucha
CTO
Neuendorfstrasse 23b
16761 Hennigsdorf
Germany

Re: K160479
Trade/Device Name: Pointershell Universal, Pointershell LS
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: February 16, 2016
Received: February 22, 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" (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

510(k) Number (if known): K160479

Device Name: Fiagon Navigation – PointerShell Universal , PointerShell LS

Indications for Use:

The PointerShell Universal and PointerShell LS are 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.

Both 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.
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)

510(k) Summary

February 16, 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 – PointerShell Universal, PointerShell LS
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 geometrically modified instrument for the Image Guided Surgery. The instruments involved in this submission are a modified version of instruments that have been approved within Fiagon Navigation extended instrument Set ENT (K141456).

4. Predicate Device Information

The device described in this submission is substantially equivalent to the following comparable unmodified devices:

	Predicate Device / legally marketed device	**Manufacturer**	**510(k) No.**
1	Fiagon Navigation Extended Instrument Set ENT Component **PointerShell 3mm, 4mm and 5mm**	Fiagon GmbH	K141456

5. Device Description

The Fiagon Navigation – PointerShell Universal and PointerShell LS are reusable instruments intended to be used with the Fiagon Navigation system. The instruments are electromagnetically navigated devices that are

a. Instrument adapters (designed for mechanical connection to shavers or surgical instruments with different diameters without motor).

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)

6. List of components

Components	Grouping	Sterility State
PointerShell Universal	Instrument Adapter	• user sterilized, • reusable, • delivered in non-sterile state
PointerShell LS	Instrument Adapter	• user sterilized, • reusable, • delivered in non-sterile state

7. Intended Use

The PointerShell Universal and PointerShell LS are 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.
It 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.

8. Comparison of Technological Characteristics

The substantial equivalence of the PointerShell Universal and PointerShell LS to the PointerShell 3mm, 4mm and 5mm are shown by similarities in their intended use, indications for use, materials, and performance.

All devices utilize:

- Electromagnetic tracking technology for navigation included in surgical instruments
- Are adapters for instruments for enabling image guidance

The primary difference between the unmodified devices and the new devices is change in the shaft diameter of the devices. While the PointerShell 3mm, 4mm and 5mm incorporate devices of their respective diameters, the PointerShell Universal is a combination of all these 3 devices in one. It incorporates instruments of shaft diameters ranging from 2.5mm to 5mm.The PointerShell LS is used for navigation of octagonal shavers or octagonal surgical instruments with a maximum shaft diameter of 6mm. These changes do not raise new issues of safety and effectiveness.

9. Performance Data

Testing was performed in order to determine device precision and accuracy. The following nonclinical tests were performed to determine substantial equivalence:

A mean bench accuracy as target registration error of 1.1 mm for Pointershell Universal and 1.1 mm for PointerShell LS was measured for the new devices, which compares to the values mean < 1.5 mm for the predicate devices in an identical test setup.

The results support the claim of substantial equivalence to the unmodified devices.

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

10. Conclusion

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the PointerShell Universal and the PointerShell LS have been shown to be substantially equivalent to the comparable devices PointerShell 3mm, 4mm and 5mm and does not present any new issues of safety or effectiveness.