March 10, 2020

Fiagon GmbH
Dirk Mucha, CTO
Neuendorfstrasse 23b
Hennigsdorf, DE 16761 Brandenburg

Re: K200041
Trade/Device Name: FlexPointer 1.5 Single Use, FlexTube 3 Single Use
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: February 13, 2020
Received: February 14, 2020

Dear Dirk 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200041

Device Name

Fiagon Navigation – FlexPointer 1.5 Single Use, FlexTube 3 Single Use

Indications for Use *(Describe)*

The devices FlexPointer 1.5 Single Use and FlexTube 3 Single Use are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The devices are indicated for use with the Fiagon Navigation system using electromagnetic navigation.

The devices 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

January, 6 2020

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 – FlexPointer 1.5 Single Use, FlexTube 3 Single Use
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 instrument, Fiagon Navigation – FlexPointer 1.5 (K150473) and FlexTube 3mm (K141456)

4. Predicate Device Information

Fiagon Navigation – FlexPointer 1.5 (K150473) and FlexTube 3mm (K141456) (in extended instrument set ENT)

5. Device Description

The Fiagon Navigation – FlexPointer 1.5 Single Use and FlexTube 3 Single Use are disposable instruments intended to be used with the Fiagon Navigation system. The FlexPointer 1.5 Single Use is an electromagnetically navigated pointing device (malleable, sensor within the tip). The FlexTube 3 Single Use is an electromagnetically navigated suction device (malleable, sensor within the tip).
Each device incorporates a sensor device, 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. Indications for Use

The devices FlexPointer 1.5 Single Use and FlexTube 3 Single Use are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The devices are indicated for use with the Fiagon Navigation system using electromagnetic navigation.

The devices 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.

7. Comparison of Technological Characteristics

The FlexPointer 1.5 Single Use is a modified version of the previously cleared FlexPointer 1.5 (K150473). The FlexTube 3 Single Use is a modified version of the previously cleared FlexTube 3mm (K141456). The reason for this Special 510(k) is to describe a change in material as well as a change from a reprocessed device to one that is provided sterile and is Single Use and disposable.

The new devices, FlexPointer 1.5 Single Use and FlexTube 3 Single Use, have very similar technological characteristics compared to the predicate devices. All instruments are navigation instruments and utilize the same sensors for spatial measurement and work equally well with the Fiagon Navigation System.

The new devices utilize a different connector housing material (PSU). The old material used for the connector housing in the predicate device was PEI. The design of the plug remains identical so that the proper connection to the navigation system is not affected by the change in materials.

For the device FlexPointer 1.5 Single Use the handle is slightly modified and uses different material compared to its predicate.
The design change of the handle consist of some more rounded planes to increase ergonomics making use of the designing possibilities of an injected molding plastic part compared to a machined stainless steel part. The modified material results in a lighter design of the instrument increasing the ergonomics.
The new material compositions have been assessed to biocompatibility concerns with identical endpoint tests to the predicate and can be seen substantially equivalent to the predicate.

For the FlexTube 3 Single Use the navigation sensor is supported within an additional heat shrink tubing on the outside of a stainless steal tube, where the predicate uses an additional tube as sensor carrier which is fixed inside the stainless steel tube. Therefore, even though the inner diameter in the modified instrument is comparable in dimensions to the unmodified instrument, there is no additional obstruction inside the inner tube, thereby facilitating the ease of flow of fluids within the instruments. Further, the performance testing demonstrates that the instruments perform as expected. Thus, the modified device can be considered substantially equivalent with respect to technological characteristics.

The handle is slightly modified and uses different material. The design change of the handle consist of some more rounded planes to increase ergonomics making use of the designing possibilities of an injected molding plastic part compared to a machined stainless steel part. The modified material results in a lighter design of the instrument increasing the ergonomics. The new material compositions (incl. new handle, heat shrink and the unmodified suction tube) have been assessed to biocompatibility concerns with identical endpoint tests to the predicate and can be seen substantially equivalent to the predicate.
The material change does not raise new concerns of safety or effectiveness.

The change of material in the plug and handle as well as the modified sensor fixation with additional heat shrink tubing are motivated by the change of the sterilization method from

steam sterilization (132° C) to ETO sterilization and from 10 times use to single use, which is lowering the requirements for the temperature stability of the materials.
Under the modified sterilization and life time specifications the material modifications do not raise new concerns of safety or effectiveness.

Sterilization validation tests reports are provided to demonstrate that these differences do not raise new issues of safety and effectiveness

Biocompatibility tests have been performed to demonstrate substantial equivalent to the predicates and bench testing of performance have been done using same test protocols for navigation accuracy with the Fiagon Navigation system on a anatomical phantom. Mean accuracy value < 1.5 mm is achieved for both new devices which compares to the predicates.

8. Performance Data

Bench testing was performed in order to determine device accuracy of the modified devices with the Fiagon Navigation system.
Also testing was performed to ensure sterilization of the modified disposable instruments does not alter the performance characteristics of the device.
Following test were performed:

- Bench test: Accuracy on anatomical phantom with the Fiagon navigation system
  Result: mean accuracy < 1.5 mm as mean target registration error on fiducial markers.
  Protocol: total 15 x 15 fiducial markers are touched on anatomical skull phantom and measured/displayed navigation position by device is compared to known position of marker. Difference of all 225 trial is computed as mean accuracy.
- Bench test: Post sterilization accuracy testing: same protocol as above was used post sterilization and accelerated aging.
  Result: mean accuracy < 1.5 mm as mean target registration error on fiducial markers.

9. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the devices FlexPointer1.5 Single Use and FlexTube 3 Single Use have been shown to be substantially equivalent to the predicate devices FlexPointer 1.5 and FlexTube 3mm and the modified devices do not present any new issues of safety or effectiveness.