July 19, 2021

Fiagon GmbH
Dirk Mucha
Chief Technology Officer
Neuendorfstrasse 23b
16761 Hennigsdorf, Brandenburg
Germany

Re: K211291
Trade/Device Name: Cube Navigation System, VirtuEye V2, Navigation Sensor NanoRest, Navigation Unit Cube 4D
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: PGW
Dated: April 23, 2021
Received: April 28, 2021

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 Shu-Chen Peng
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211291

Device Name
Cube Navigation System
Navigation Unit Cube 4D, VirtuEye V2, Navigation Sensor NanoRest

Indications for Use *(Describe)*
The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K211291

June 24, 2021

1. Submitter Information

Submitter: Fiagon GmbH
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Telephone: +49 3302 201 21 10
Telefax: +49 3302 201 21 15

Contact: Dirk Mucha
Chief Technology Officer

2. Device Information

Trade Name:	Cube Navigation System *Navigation Unit Cube 4D* *VirtuEye V2* *Navigation Sensor NanoRest*
Common Name:	Image guided surgery system
Classification:	Class II per 21 CFR 882.4560
Classification Name:	Ear, Nose, and Throat Stereotaxic Instrument
Product Code:	PGW

3. Predicate Device Information

The Cube navigation system is substantially equivalent to the following predicate devices:

- Fiagon Navigation system (K162176) - primary
- Fiagon Navigation system (K133573) – secondary

4. Device Description

The Cube Navigation System is an image guided surgery system, visualizing instrument positions on 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, called navigation sensor within the Cube navigation system. 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 surface matching performed by the user either tactile using an navigated instrument or non-tactile using the registration device VituEye. 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.

5. Intended Use

The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 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

Indications for Use Cube Navigation System and Predicate Devices

Device	Indications for Use
Cube Navigation System	The Cube Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 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.

Device	Indications for Use
	Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies. ENT related anterior skull base procedures
Fiagon Navigation System (K162176)	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
Fiagon Navigation System (K133573)	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

6. Comparison of Technological Characteristics

The Cube Navigation System is considered to be substantially equivalent to the previously cleared Fiagon Navigation system (K162176 and K133573).

The system comprises modified components of Hardware and Software to previously cleared Fiagon Navigation System (K162176 and K133573) which do not change indications for use, intended use or performance and safety requirements. The functionality of the overall system remains equal to the Fiagon Navigation System. More details about identical and modified hardware and software are described subsequentially.

The main difference of the new Cube navigation system to its predicates are mostly dimensional differences with aesthetic changes in the overall design and updated versions of internal computing hardware. Additionally, the Fiagon navigation system (predicate) allows for importing/loading image data from CD/DVD drive incorporated in the system.
The Cube navigation system tracking technology, system components, registration methods, and system functionality however are identical to the primary predicate.

One difference of the new Cube navigation system is that the new system offers an additional design and component as the navigation sensor (also known as field generator) for the system. The Navigation sensor NanoRest can be used as an alternative to the already cleared navigation sensor components with the predicate devices. The additional alternative NanoRest has the same technological characteristics and functionality as the other navigation sensor options. The generating device has a smaller working field with similar accuracy and the design allows adjusting the working field to include the relevant surgical area (similar as for the design of the predicates).

Another difference of the new system is in the registration device used for non-tactile photo registration. The new Cube navigation system uses the VirtuEye component for photo registration where the camera and MapperFrame are designed into one device, where the primary predicate used two separate devices. Both versions use the same reference marker frame and underlying concept with the same algorithms. The modified device is compatible to a stereo camera to allow for taking pictures simultaneous, where the primary predicate is compatible to a single camera device for taking pictures sequencially.

The Navigation software ENT released for the Cube navigation system is the latest release in the release history of the Fiagon navigation software ENT initially cleared for the predicates Fiagon Navigation systems. The visualization concept of the orthogonal slice images, the 3D model, the live video image and the status indicators in the software remained similar to the originally cleared Navigation Software ENT. The latest release for Cube Navigation systems has undergone a UI refresh with symbols and icons being updated for improved user visualization.

The software features of the latest release of the navigation software ENT includes the similar set of functionalities of the predicate systems. Such as Recording function (recording sequences of screen contents), Screen shot function, Patient data loading via USB device, PACS Network, Image data fusion, Determine distances between two points in the data set, overlaying structures, Visualization parameters of the navigation display can be adjusted (instrument specific). Additionally, the Cube navigation system allows for removing artifacts from the 3D model (eye protection glasses) in order to use the dataset for registration.

The different functionalities are supplementary functions and do not limit or change the main functionality of the system.

The modifications do not raise new types of safety or effectiveness questions. Bench testing has been conducted to evaluate the proposed system, and results confirm that the device performs as intended and in a similar manner compared to the predicate.

Feature	Cube Navigation System	Fiagon Navigation System [K162176]	Fiagon Navigation System [K133573]
Class	Class II 21 CFR 882.4560 Product code: PGW	Class II 21 CFR 882.4560 Product code: PGW	Class II 21 CFR 882.4560 Product code: PGW
Indications for Use	(see above)	(see above)	(see above)
Tracking Method	Electromagnetic	Electromagnetic	Electromagnetic
Field generator	Mounted to headrest, Integrated into headrest or bedside mounted	Integrated into headrest or bedside mounted	Integrated into headrest or bedside mounted
Method of registration	Surface matching tactile Surface matching photo	Surface matching tactile Surface matching photo	Surface matching tactile
System accuracy requirement	Mean bench accuracy: Position Mean < 1.5mm	Mean bench accuracy: Position Mean < 1.5mm	Mean bench accuracy: Position Mean < 1.5mm
Field distortion detecting mechanism	Yes; Field distortions are detected by redundant localizer information and distorted values are excluded from displaying	same	same
Instrument verification	Instrument /Registration verified after patient registering. User needs to confirm on anatomical landmark.	Same	same
Safety and EMC	Meets IEC 60601-1 :2012. IEC 60601-1-2:2014	Meets IEC 60601-1 :2012 IEC 60601-1-2:2014	Meets IEC 60601-1 IEC 60601-1-2
Programming language	C++	C++	C++

7. Performance Data

Tests were performed in order to prove the performance claims such as, device precision & accuracy, electrical safety, EMC and the electromagnetic field distortion detection mechanism. The following non-clinical tests were performed to determine substantial equivalence:

- Anatomy orientated accuracy bench testing for each instrument probe and localizer without registration in order to measure the instrument accuracy achieved with the Cube Navigation System itself.
- Anatomy orientated accuracy bench testing after tactile registration photo based, non-tactile registration
- Fields distorting handling bench testing
- Electrical safety according to IEC 60601-1 and EMC testing according to IEC 60601-1-2
- The non-clinical data supports the safety and performance of the device, thus demonstrating that the Cube Navigation System performs as intended in the specified use conditions.
- The non-clinical data demonstrates that the device performs comparably to the predicate device for the same intended use.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, it is concluded that the Cube Navigation system is substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.