June 2, 2026

Fiagon GmbH
Magdalena Giba
Head of Quality and Regulatory
Neuendorfstr. 23b
Hennigsdorf, Brandenburg 16761
Germany

Re: K261540
Trade/Device Name: Cube 4D Navigation System, VirtuEye Pro
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: May 8, 2026
Received: May 8, 2026

Dear Magdalena Giba:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JOYCE C.
LIN -S

for Shu-Chen Peng, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261540

Please provide the device trade name(s).

Cube 4D Navigation System, VirtuEye Pro

Please provide your Indications for Use below.

The Cube 4D Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 4D 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;
• Transsphenoidal 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

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

May 8, 2026

1. Submitter Information

Submitter: Fiagon GmbH
Address: Neuendorfstrasse 23b
16761 Hennigsdorf, Germany

Telephone: +49 3302 201 21 10

Contact: Ms. Magdalena Giba
Head of Quality and Regulatory

2. Device Information

Trade Name:	Cube 4D Navigation System *VirtuEye Pro*
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 4D Navigation System is substantially equivalent to the following predicate device:

- Cube Navigation System (K211291)

4. Device Description

The Cube 4D Navigation System is an image guided surgery system, visualizing instrument positions on preoperative scans (e.g., CT, MRI) 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 4D Navigation System. The principle of navigation is based on electromagnetic spatial measuring of localizer elements in a generated electromagnetic field.
The display of navigation information requires an image-to-patient registration procedure. During the 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 a navigated instrument or non-tactile using the registration device VirtuEye or VirtuEye Pro. Thereafter the spatial position of the instrument is displayed superimposed to the image data.

5. Intended Use

The Cube 4D Navigation System and its components are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. The Cube 4D 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;
Transsphenoidal 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 4D Navigation System and Predicate Device

Device	Indications for Use
Cube 4D Navigation System	The Cube 4D 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
Cube Navigation System (K211291)	The Cube 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; Transsphenoidal access procedures. Intranasal procedures. Sinus procedures, such as Maxillary antrostomies, Ethmoidectomies, Sphenoidotomies/Sphenoid explorations, Turbinate resections, and Frontal sinusotomies.

Device	Indications for Use
	ENT related anterior skull base procedures

6. Comparison of Technological Characteristics

The Cube 4D Navigation System with VirtuEye Pro is considered to be substantially equivalent to the previously cleared Cube Navigation system with VirtuEye V2 (K211291).

The system comprises an additional optional component of hardware and modified software to previously cleared Cube Navigation System (K211291), which does not change indications for use, intended use or performance and safety requirements. The functionality of the overall system remains equal to the predicate device.

The main difference of the Cube 4D Navigation System to its predicate is in the registration device used for non-tactile photo registration. The new navigation system adds the VirtuEye Pro component for photo registration, which is a more compact device that serves the same purpose as the component VirtuEye V2 of the predicate. The VirtuEye Pro device does not require a MapperFrame for determination of the position any longer.
Both devices use the same underlying concept of stereo camera generated point-cloud information with connected position information. The VirtuEye Pro device uses a newer stereo camera configuration that allows for recording the target area in higher resolution.

The Cube 4D Navigation Software released for the Cube 4D Navigation System is the latest release in the release history of the navigation software for ENT initially cleared for the predicates Cube 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 the same to the originally cleared Navigation Software ENT. The latest release for Cube 4D Navigation Systems integrates functionalities of the new component VirtuEye Pro without changing primary navigation functionality.

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 4D Navigation System, VirtuEye Pro	Cube Navigation System, VirtuEye V2 [K211291]
Class	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)
Tracking Method	Electromagnetic	Electromagnetic
Method of registration	Surface matching tactile Surface matching photo	Surface matching tactile Surface matching photo

Feature	Cube 4D Navigation System, VirtuEye Pro	Cube Navigation System, VirtuEye V2 [K211291]
System accuracy requirement	Mean bench accuracy: Position Mean < 1.5mm	Mean bench accuracy: Position Mean < 1.5mm
Field distortion detecting mechanism	Yes	Yes
Instrument verification	Instrument /Registration verified after patient registering. User needs to confirm on anatomical landmark.	Instrument /Registration verified after patient registering. User needs to confirm on anatomical landmark.
Safety and EMC	Meets IEC 60601-1 :2020 IEC 60601-1-2:2020	Meets IEC 60601-1 :2012 IEC 60601-1-2:2014
Programming language	C++	C++

7. Performance Data

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

-Anatomy orientated accuracy bench testing after photo registration

-Electrical safety according to IEC 60601-1

-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 4D 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 predicate, it is concluded that the Cube 4D Navigation System is substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.