February 25, 2022

FEops nv
% Niels Festjens
RA Consultant
OrthoGrow nv
Davincilaan 1
Zaventem, Flemish-Brabant 1930
Belgium

Re: K214066
Trade/Device Name: FEops HEARTguide
Regulation Number: 21 CFR 870.1405
Regulation Name: Interventional cardiovascular implant simulation software device
Regulatory Class: Class II
Product Code: QQI
Dated: December 23, 2021
Received: December 27, 2021

Dear Niels Festjens:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K214066

Device Name
FEops HEARTguide

Indications for Use *(Describe)*
FEops HEARTguide™ is indicated for patient-specific simulation of transcatheter left atrial appendage occlusion (LAAO) device implantation during procedural planning.

The software performs computer simulation to predict implant frame deformation to support the evaluation for LAAO device size and placement.
FEops HEARTguide™ is intended to be used by qualified clinicians in conjunction with the simulated device instructions for use, the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.
FEops HEARTguide™ is not intended to replace the simulated device instructions for use for final LAAO device selection and placement.

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 (21CFR807.92)

SUBMITTER

Company Name:	FEops nv
Establishment registration number:	3020703662
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Phone number:	+32486435671
Principal contact person:	Niels Festjens
Principal contact e-mail address	niels@ortho-grow.com
Additional contact person:	Peter Mortier
Additional contact e-mail address	peter.mortier@feops.com

Summary date:

DEVICE

Name & trade name:	FEops HEARTguide™
Classification name:	Interventional Cardiovascular Implant Simulation Software Device

PREDICATE DEVICE

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	FEops HEARTguide™
De Novo class II petition:	DEN200030
Decision date	08 SEP 2021
Classification product code	QQI
Regulation Number	870.1405
Manufacturer	FEops NV

DESCRIPTION AND FUNCTIONING OF THE DEVICE

FEops HEARTguide™ predicts implant frame deformation after percutaneous LAAO device implantation through computer simulation. The predicted deformation provides additional information during LAAO procedural planning.

The simulation is based on a 3D model of the patient anatomy which is generated from 2D medical images of the patient anatomy (multi-slice Cardiac Computed Tomography). The simulation is executed by FEops Case Analysts and run on FEops infrastructure.

The simulation report is created by combining a predefined device model with a patient-specific model of the patient anatomy. This is performed by trained operators at FEops using an internal software platform through an established workflow. The purposely qualified case analysts and quality control analysts process the received medical images of the patient to produce the simulation results.

The simulation results are provided as 2D and numerical data shown in a PDF report and 3D, 2D and numerical data shown in a web-based Viewer application accessible through a standard web browser.

INTENDED USE

FEops HEARTguide™ is indicated for patient-specific simulation of transcatheter left atrial appendage occlusion (LAAO) device implantation during procedural planning.

The software performs computer simulation to predict implant frame deformation to support the evaluation for LAAO device size and placement.
FEops HEARTguide™ is intended to be used by qualified clinicians in conjunction with the simulated device instructions for use, the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.
FEops HEARTguide™ is not intended to replace the simulated device instructions for use for final LAAO device selection and placement.

FEops HEARTguide™ is prescription use only.

TECHNOLOGICAL CHARACTERISTICS

The subject device shares the same code base as the predicate device and differs in the addition of computer models for two additional LAAO devices, the Abbott Amplatzer Amulet (AMU) and the Boston Scientific Watchman FLX (FLX).

	Predicate device	**Subject Device**	**Comparison**
Device Name	FEops HEARTguide™	FEops HEARTguide™	/
510(k)/De Novo Number	DEN200030	K214066	/
Manufacturer	FEops nv	FEops nv	Same
Regulation Number	21 CFR 870.1405	21 CFR 870.1405	Same
Device Classification Name	Interventional cardiovascular implant simulation software device	Interventional cardiovascular implant simulation software device	Same
Common name	FEops HEARTguide™	FEops HEARTguide™	Same
Product Code	QQI	QQI	Same
Intended Use/Indications for Use	FEops HEARTguide is indicated for patient-specific simulation of transcatheter left atrial appendage occlusion (LAAO) device implantation during procedural planning. The software performs computer simulation to predict implant frame deformation to support the evaluation for LAAO device size and placement. FEops HEARTguide is intended to be used by qualified clinicians in conjunction with the simulated device instructions-for-use, the patient's clinical history, symptoms, and other	FEops HEARTguide is indicated for patient-specific simulation of transcatheter left atrial appendage occlusion (LAAO) device implantation during procedural planning. The software performs computer simulation to predict implant frame deformation to support the evaluation for LAAO device size and placement. FEops HEARTguide is intended to be used by qualified clinicians in conjunction with the simulated device instructions-for-use, the patient's clinical history, symptoms, and other	Same

	preprocedural evaluations, as well as the clinician's professional judgment. FEops HEARTguide is not intended to replace the simulated device's instructions for use for final LAAO device selection and placement. FEops HEARTguide is prescription use only.	preprocedural evaluations, as well as the clinician's professional judgment. FEops HEARTguide is not intended to replace the simulated device's instructions for use for final LAAO device selection and placement. FEops HEARTguide is prescription use only.	
Prescription Use only	Yes	Yes	Same
Software build	1.4.1	1.4.2	Changes limited to extension of device library and optimization of FLX and AMU modelling strategy
Modelling strategy	Device specific computational model applied to patient-specific geometry	Device specific computational model applied to patient-specific geometry	Same
Software architecture	Simulation results prepared by FEops Case Analysts and made available in Web based Viewer	Simulation results prepared by FEops Case Analysts and made available in Web based Viewer	Same
Simulated devices	1. Boston Scientific WATCHMAN (P130013)	1. Boston Scientific WATCHMAN (P130013) 2. Boston Scientific WATCHMAN FLX (P130013/S035) 3. Abbott Amplatzer Amulet (P200049)	The subject device library has 2 additional LAA occluders to select. All 3 included LAA occluders are approved for use on the US market.

The provided detailed comparison demonstrates the subject device is substantially equivalent in intended use, design, operating principles, materials and performance characteristics to the primary predicate device. The difference in technological characteristics do not raise new questions of safety and effectiveness.

PERFORMANCE DATA

The 510(k)-submission includes data to demonstrate the Special Controls defined in 21CFR870.1405 are implemented, including:

- Software verification, validation, and hazard analysis, with identification of appropriate mitigations, including full verification and validation of the software according to the pre-defined software specifications with detail expected for a moderate level of concern software,
- A detailed credibility assessment of the device models demonstrating computational modeling verification and validation activities have been performed to establish the predictive capability of the device for its indications for use. The applied methods and results are similar to the activities performed for the predicate device,
- The provided performance validation testing data shows the applied methods are similar to the methods applied for the design validation of the predicate device and a similar performance level has been demonstrated. The data includes a comparison of the results to clinical data supporting the indications for use to demonstrate accuracy and clinical meaningfulness of the simulations, an assessment of the agreement between the computational model results and clinical data across the full intended operating range, a justification of the endpoints and sample sizes determination and clinical meaningfulness
- To ensure consistency of modeling outputs, the validation was performed with multiple qualified operators using the procedure that will be implemented under anticipated conditions of use and the factors which were held constant where identified.
- A detailed description of the computations and statistical analyses used to evaluate the data is included in the 510(k) submission,
- A Human factors evaluation report was provided demonstrating the ability of the user interface and labeling to allow for intended and qualified users to correctly use the device and interpret the provided information
- Device labeling is included in the submission which includes warnings that identify anatomy and image acquisition factors that may impact simulation results, provide cautionary guidance for interpretation of the provided simulation results, describes the device simulation inputs and outputs, and key assumptions made in the simulation and determination of simulated outputs as well as the computational modeling performance of the device for presented simulation outputs, and the supporting evidence for this performance

For both added LAAO devices, the performance study was performed on a cohort with a sample size equal to or larger than the predicate device. Acceptance criteria were defined using the same method as for the predicate device demonstrating the same clinical meaningfulness. The same type of measurements and an identical statistical analysis was performed. This demonstrates the performance of the subject device is equivalent to the performance of the predicate device.

SUMMARY

The characteristics that determine the functionality and performance of FEops HEARTguide™, the subject device, are substantially equivalent to the predicate device cleared under DEN200030. The testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.