



September 8, 2021

FEops NV  
% Niels Festjens  
Senior Quality and Regulatory Affairs consultant  
OrthoGrow NV  
Davincilaan 1  
Zaventem, Vlaams-Brabant 1930  
Belgium

Re: DEN200030

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: May 5, 2020

Received: May 7, 2020

Dear Niels Festjens:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the FEops HEARTguide, a prescription device under 21 CFR Part 801.109 with the following 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 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the FEops HEARTguide, and substantially equivalent devices of this generic type, into Class II under the generic name interventional cardiovascular implant simulation software device.

FDA identifies this generic type of device as:

**Interventional cardiovascular implant simulation software device.** An interventional cardiovascular implant simulation software device is a prescription device that provides a computer simulation of an interventional cardiovascular implant device inside a patient's cardiovascular anatomy. It performs computational modeling to predict the interaction of the interventional cardiovascular implant device with the patient-specific anatomical environment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On May 7, 2020, FDA received your De Novo requesting classification of the FEops HEARTguide. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the FEops HEARTguide into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the FEops HEARTguide can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Inaccurate simulation results leading to selection of suboptimal treatment plan, leading to prolonged procedure time and/or patient injury	Software verification, validation, and hazard analysis Computational modeling verification and validation Performance validation with clinical data Labeling Human factors testing
Delayed delivery of results due to software failure or use error, leading to delay of treatment	Software verification, validation, and hazard analysis Human factors testing Labeling
Failure to properly interpret device results leading to selection of suboptimal treatment plan, leading to prolonged procedure time and/or patient injury	Human factors testing Labeling

In combination with the general controls of the FD&C Act, the interventional cardiovascular implant simulation software device is subject to the following special controls:

- (1) Software verification, validation, and hazard analysis, with identification of appropriate mitigations, must be performed, including a full verification and validation of the software according to the pre-defined software specifications.
- (2) Computational modeling verification and validation activities must be performed to establish the predictive capability of the device for its indications for use.
- (3) Performance validation testing must be provided to demonstrate the accuracy and clinical relevance of the modeling methods for the intended implantation simulations, including the following:
  - (i) Computational modeling results must be compared to clinical data supporting the indications for use to demonstrate accuracy and clinical meaningfulness of the simulations;
  - (ii) Agreement between computational modeling results and clinical data must be assessed and demonstrated across the full intended operating range (e.g., full range of patient population, implant device sizes and patient anatomic morphologies). Any selection criteria or limitations of the samples must be described and justified;
  - (iii) Endpoints (e.g., performance goals) and sample sizes established must be justified as to how they were determined and why they are clinically meaningful; and
  - (iv) Validation must be performed and controls implemented to characterize and ensure consistency (i.e., repeatability and reproducibility) of modeling outputs:
    - (A) Testing must be performed using multiple qualified operators and using the procedure that will be implemented under anticipated conditions of use; and
    - (B) The factors (e.g., medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data.
- (4) Human factors evaluation must be performed to evaluate the ability of the user interface and labeling to allow for intended users to correctly use the device and interpret the provided information.
- (5) Device labeling must be provided that describes the following:
  - (i) Warnings that identify anatomy and image acquisition factors that may impact simulation results and provide cautionary guidance for interpretation of the provided simulation results;
  - (ii) Device simulation inputs and outputs, and key assumptions made in the simulation and determination of simulated outputs; and
  - (iii) The computational modeling performance of the device for presented simulation outputs, and the supporting evidence for this performance.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact [CDRHProductJurisdiction@fda.hhs.gov](mailto:CDRHProductJurisdiction@fda.hhs.gov).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the interventional cardiovascular implant simulation software device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Judy Ji at 301-796-6949.

Sincerely,

for Bram Zuckerman, M.D.  
Director  
OHT2: Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health