November 25, 2025

FEops nv
Franky Dubois
QARA Manager
Technologiepark-Zwijnaarde 122
Gent, 9052
Belgium

Re: K250635
Trade/Device Name: FEops HEARTguide Simulation Application
Regulation Number: 21 CFR 870.1405
Regulation Name: Interventional Cardiovascular Implant Simulation Software Device
Regulatory Class: Class II
Product Code: QQI
Dated: October 17, 2025
Received: October 27, 2025

Dear Franky Dubois:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Katherine N. Trivedi -S
Digitally signed by Katherine N. Trivedi -S
Date: 2025.11.25 14:58:05 -07'00'

Katherine Trivedi
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)*
K250635

Device Name
FEops HEARTguide™ Simulation Application

Indications for Use *(Describe)*
FEops HEARTguide™ Simulation Application 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™ Simulation Application 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™ Simulation Application 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.

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

1.1 Submitter

Company Name:	FEops nv
Establishment registration number:	3020703662
Address:	Technologiepark-Zwijnaarde 122, 9052 Gent, Belgium
Phone number:	+32492501951
Principal contact person:	Franky Dubois
Principal contact e-mail address:	franky.dubois@materialise.be
Additional contact person:	Peter Mortier
Additional contact e-mail address:	peter.mortier@materialise.be

Summary date: October 3, 2025

1.2 Device

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

1.3 Predicate Device

The predicate device to which substantial equivalence is claimed:

Item	Description
Device Classification Name	Interventional Cardiovascular Implant Simulation Software Device
Premarket notification number	K214066
Trade or proprietary or model name	FEops HEARTguide
Original Applicant	FEops nv
Regulation Number	870.1405
Decision date	February 25, 2022
Classification product code	QQI
Classification Panel	Cardiovascular

1.4 Description and functioning of the device

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

The information provided by FEops HEARTguide™ Simulation Application 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.

The customer (clinician) does not interact with the simulation software directly. The simulations are performed by trained FEops case analysts through an established workflow. Based on a patient-specific 3D model of the anatomy, a computational model of the anatomy is generated and combined with a predefined computational model of the device.

The simulation results are delivered to the customer through the medical device FEops HEARTguide™ ALPACA (FEops - K223855) in the form of 3D model visualizations and a PDF report. All results are accessible through a standard web browser. The customer cannot modify the simulation results nor run additional simulations.

1.5 Intended Use

FEops HEARTguide™ Simulation Application 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™ Simulation Application 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™ Simulation Application is not intended to replace the simulated device instructions for use for final LAAO device selection and placement.
FEops HEARTguide™ Simulation Application is prescription use only.

1.6 Technological Characteristics

The subject device is compared to the previous cleared FEops HEARTguide™. The change on the subject device is the addition of the Boston Scientific Watchman FLX Pro device.

	Predicate device	Subject Device	Comparison
Name	FEops HEARTguide™	FEops HEARTguide™ / FEops HEARTguide™ Simulation Application	/
510(k)/De Novo Number	K214066	Subject Device	/
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
Product Class	II	II	Same
Review Advisory Panel	Cardiovascular	Cardiovascular	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,	FEops HEARTguide™ Simulation Application 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™ Simulation Application is intended to be used by qualified clinicians in conjunction with the simulated device instructions for use, the patient's clinical	Adding the Boston Scientific Watchman FLX Pro 40mm device

	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.	history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment. FEops HEARTguide™ Simulation Application is not intended to replace the simulated device instructions for use for final LAAO device selection and placement. FEops HEARTguide™ Simulation Application is prescription use only.	
Prescription Use only	Yes	Yes	Same
Software build	1.4.2	4.0.0	Releases in between were documented through LTF
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) 2. Boston Scientific WATCHMAN FLX (P130013/S035) 3. Abbott Amplatzer Amulet (P200049)	1. Boston Scientific WATCHMAN (P130013/S043) 2. Boston Scientific WATCHMAN FLX (P130013/S068) 3. Boston Scientific WATCHMAN FLX Pro (P130013/S068)	The subject device includes 1 additional LAAO device. The WATCHMAN FLX and FLX Pro have the same device frame, and the same modelling strategy is therefore used for both device variants. The subject device

		4. Abbott Amplatzer Amulet (P200049/S004)	includes a new device model for FLX Pro size 40 mm, which is not available for WATCHMAN FLX.

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.

1.7 Performance Data

Clinical performance data was included in the 510(k)-submission demonstrating FEops HEARTguide™ Simulation Application has been validated for its intended use. The applied methods are similar to the methods applied for the design validation of the predicate device and similar performance has been demonstrated.

1.8 Summary

The characteristics that determine the functionality and performance of FEops HEARTguide™ Simulation Application, the subject device, are substantially equivalent to the predicate device cleared under 510(k) K214066. The testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.