FEops nv
℅ Mieke Janssen
RA Consultant
OrthoGrow nv
Davincilaan 1
Zaventem, Flemish-Brabant 1930
BELGIUM

June 6, 2023

Re: K223855
Trade/Device Name: FEops HEARTguide™, FEops HEARTguide™ ALPACA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: May 17, 2023
Received: May 17, 2023

Dear Mieke Janssen:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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)*
K223855

Device Name
FEops HEARTguide™
FEops HEARTguide™ALPACA

Indications for Use *(Describe)*
FEops HEARTguide™ ALPACA enables visualization and measurement of structures of the heart and vessels for preprocedural planning and sizing of structural heart interventions.

To facilitate the above, FEops HEARTguide™ ALPACA provides general functionality such as:
• Segmentation of cardiovascular structures
• Visualization and image reconstruction techniques: 2D review, MPR
• Measurement and annotation tools
• Reporting tools

FEops HEARTguide™ ALPACA also allows visualization of output generated by other medical device software (e.g., FEops HEARTguide™ Simulation Application cleared as K214066).

The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.

FEops HEARTguide™ ALPACA is not intended to replace the implant device instructions for use for final LAAO and TAVI 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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K223855

510(K) SUMMARY (21CFR807.92)

SUBMITTER

Company Name:	FEops nv
Establishment registration number:	3020703662
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Principal contact e-mail address	mieke@ortho-grow.com
Additional contact person:	Peter Mortier
Additional contact e-mail address	peter.mortier@feops.com

Summary date: June 6, 2023

DEVICE

Name & trade name:	FEops HEARTguide™, FEops HEARTguide™ ALPACA
Common name:	FEops HEARTguide™
Classification name:	Picture Archiving and Communications System
Regulatory class:	II
Regulation number:	21 CFR 892.2050
Product code:	QIH

PREDICATE DEVICE

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	3mensio Workstation/3mensio Structural Heart/3mensio Vascular
510(k) number:	K153736
Decision date	May 27, 2016
Classification product code	LLZ
Regulation Number	21 CFR 892.2050
Manufacturer	Pie Medial Imaging BV

DESCRIPTION AND FUNCTIONING OF THE DEVICE

FEops HEARTguide™ ALPACA enables visualization and measurement of structures of the heart and vessels for preprocedural planning and sizing of structural heart interventions.

The software is used in a service-based business model: the customer (clinician) provides the necessary input data, FEops prepares the anatomical analysis, and delivers the results to the customer.

The results of the anatomical analysis are provided to the clinician via FEops HEARTguide™ ALPACA's web application. They are available in a PDF report and as interactive 3D and DICOM MPR visualizations. The web application is intended to be used by clinicians to review the results as well as to create additional landmarks and related measurements, if needed.

INTENDED USE

FEops HEARTguide™ ALPACA enables visualization and measurement of structures of the heart and vessels for preprocedural planning and sizing of structural heart interventions.

To facilitate the above, FEops HEARTguide™ ALPACA provides general functionality such as:

- Segmentation of cardiovascular structures
- Visualization and image reconstruction techniques: 2D review, MPR
- Measurement and annotation tools
- Reporting tools

FEops HEARTguide™ ALPACA also allows visualization of output generated by other medical device software (e.g. FEops HEARTguide™ Simulation Application cleared as K214066).

The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.

FEops HEARTguide™ ALPACA is not intended to replace the implant device instructions for use for final LAAO and TAVI device selection and placement.

TECHNOLOGICAL CHARACTERISTICS

Both the subject device and the predicate device are intended for visualization of medical images of the heart and allow analysis of structures of the heart and vessels. Both devices are to be used for preprocedural planning and sizing of transcatheter cardiovascular interventions. Both devices enable automatic image segmentation for which the output is reviewed and adapted if needed. The predicate device includes additional functionality for post-operative evaluation of structural heart interventions as well as tools to support clinical diagnosis by quantifying calcifications and dimensions in coronary arteries.

	Subject device	Predicate device	Comparison
Device Name	FEops HEARTguide™ ALPACA™	3mensio Workstation/3mensio Structural Heart/3mensio Vascular	/
510(k) Number	/	K153736	/
Manufacturer	FEops NV	Pie Medical Imaging BV	/
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	same
Device Classification Name	Picture archiving and communications system	Picture archiving and communications system	same
Common Name		3mensio Workstation	/
Product Code	QIH	LLZ	Similar, the subject device implements artificial intelligence including nonadaptive machine learning algorithms
Intended use	FEops HEARTguide™ ALPACA enables visualization and measurement of structures of the heart and vessels for preprocedural planning and sizing of structural heart interventions.	3mensio Workstation is a software solution that is intended to provide Cardiologists, Radiologists and Clinical Specialists additional information to aid them in reading and interpreting DICOM compliant medical images of	Same, both the subject and predicate device share the same intended use, in that they enable visualization of medical images of the heart, and analysis of structures of the heart and vessels.

	To facilitate the above, FEops HEARTguide™ ALPACA provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D review, MPR • Measurement and annotation tools • Reporting tools FEops HEARTguide™ ALPACA also allows visualization of output generated by other medical device software (e.g. FEops HEARTguide™ Simulation Application cleared as K214066). The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment.	structures of the heart and vessels. 3mensio Structural Heart enables the user to: • Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels, • Quantify calcium (volume, density) 3mensio Vascular enables the user to: • Visualize and assess stenosis, aneurisms and vascular structures • Measure the dimensions of vessels (diameters, lengths, areas, volumes, angles)	

	FEops HEARTguide™ ALPACA is not intended to replace the implant device instructions for use for final LAAO and TAVI device selection and placement.		
Indications for Use	FEops HEARTguide™ ALPACA enables visualization and measurement of structures of the heart and vessels for preprocedural planning and sizing of structural heart interventions. To facilitate the above, FEops HEARTguide™ ALPACA provides general functionality such as: • Segmentation of cardiovascular structures • Visualization and image reconstruction techniques: 2D review, MPR • Measurement and annotation tools • Reporting tools FEops HEARTguide™ ALPACA also allows visualization of output generated by other medical device software	3mensio Workstation enables visualization and measurement of structure of the heart and vessels for: - Preoperational planning and sizing for cardiovascular interventions and surgery - Postoperative evaluation - Support of clinical diagnosis by quantifying dimensions in coronary arteries - Support of clinical diagnosis by quantifying calcifications (calcium scoring) in the coronary arteries To facilitate the above, the 3mensio Workstation provides general functionality such as:	Similar, Both devices are indicated to be used for preprocedural planning and sizing of structural heart interventions. Whereas the subject device solely focuses on preprocedural planning, the predicate device additionally includes functionality for postoperative evaluation of structural heart interventions. This does not impact the indication for use for preprocedural planning. The predicate device also supports clinical diagnosis by quantifying calcifications and quantifying dimensions in coronary arteries. This functionality is not present in the subject device.

	(e.g. FEops HEARTguide™ Simulation Application cleared as K214066). The results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other preprocedural evaluations, as well as the clinician's professional judgment. FEops HEARTguide™ ALPACA is not intended to replace the implant device instructions for use for final LAAO and TAVI device selection and placement.	- Segmentation of cardiovascular structures - Automatic and manual centerline detection - Visualization and image reconstruction techniques: 2D review, Volume rendering, MPR, Curved MPR, Stretched CMPR, Slabbing, MIP, AIP, MinIP - Measurement and annotation tools - Reporting tools	
Prescription Use	Yes	Yes	same
DICOM visualization (including MPR)	Yes, CT data in DICOM format	Yes, CT data in DICOM format	same
Image segmentation	Segmentation functionality based on artificial intelligence including nonadaptive machine learning, followed by human supervision and a quality check by a FEops Case analyst.	3mensio enables automatic segmentation	Similar, both devices include human-supervised automated segmentation functionality. Both devices include the option for the physician to review the segmentation.
3D Visualization	FEops HEARTguide ALPACA includes 3D visualization of medical	3mensio includes 3D visualization of medical	Similar

	images (using 3D surfaces).	images (volume rendering).	
Landmark identification and measurements	Both manual and AI supported functions for landmark identification.	Both manual and AI supported functions for landmark identification.	Same
Scope - Structural heart interventions	Transcatheter heart interventions	Transcatheter heart interventions	Same, both devices are limited to transcatheter interventions.
Functionality for post-intervention evaluation	No	Yes	The predicate device includes functionality for post-intervention evaluation. This functionality is absent in the subject device.
Verification and Validation	Software verification and validation was performed. Documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Design verification confirmed that the system requirements were implemented correctly. Design validation established that the FEops HEARTguide ALPACA conforms to the intended use and defined user needs, demonstrating the safety	Verification showed that the system requirements – derived from the intended use and indications for use – were implemented correctly, demonstrating the effectiveness of the device. A validation plan for the final validation of the release build was executed on the final build. A test report comparing the numerical results of the device compared with the predicate devices was generated.	Same

	and effectiveness of the subject device.		
Cloud-based	Yes	No, 3mensio is a traditional software package, to be installed on a specific computer	Different, while the subject device is cloud-based, the predicate device is a traditional software package to be installed on a specific computer. FEops HEARTguide™ ALPACA is subject to cybersecurity measures (see Section 16).
Reporting tools	FEops HEARTguide generates pdf reports	3mensio generates pdf reports	Same

The provided detailed comparison demonstrates the subject device is substantially equivalent in intended use, design, operating principles and performance characteristics to the predicate device.

PERFORMANCE DATA

Non-clinical performance data was included in the 510(k)-submission demonstrating FEops HEARTguide™ ALPACA has been validated for its intended use and is substantial equivalent to the predicate device. Software verification and validation was performed, and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This includes verification against defined requirements, and validation against user needs. In addition, documentation following "Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions" was provided to demonstrate the performance of the quantitative imaging function included within FEops HEARTguide™ ALPACA. The results of the accuracy or performance validation are summarized below.

For LAAO, a study was performed on a cohort of 35 representative retrospective cases, during which quantitative outputs of FEops HEARTguide™ ALPACA were compared with manually annotated data (i.e. ground truth). The age of the studied cohort is 76.2±8.7y (50-92y), 51% were male subjects, and the LAA morphology was chicken wing (43%), reversed chicken wing (11%) or non-angulated (46%). Recent datasets representative for the intended population were used in this test cohort, covering different CT manufacturers, imaging parameters (e.g. slice thickness) and regions. No datasets were included that were used for training the AI models.

A performance goal was set for the mean diameter of the semi-automatically identified landing zone, as this is considered the most important landmark for the pre-operative planning of LAAO procedures. The maximum allowed difference in percentage must be less than the predetermined performance goal of ±18%.

The Bland-Altman analysis conducted on the mean diameter of the landing zone provided the following results for the semi-automatic and fully automatic outputs respectively:

	Semi-automatic output	Fully automatic output
Mean of differences (%)	1.4 ± 4.6	4.1 ± 7.2
Confidence interval (CI) on the mean (%)	(-0.2, 2.9)	(1.6, 6.6)
Inferior Limit of Agreement (LoA) (%)	-7.7	-10.1
Superior LoA (%)	10.4	18.3

CI on inferior LoA (%)	(-10.5, -5.0)	(-14.4, -5.8)
CI on superior LoA (%)	(7.7, 13.2)	(14.0, 22.6)

For the semi-automatically identified landing zone, the lower limit of the CI calculated on the inferior LoA (-10.5%) and the upper limit of the CI calculated on the superior LoA (13.2%) are within the maximum allowed difference of ±18%, so the performance goal has been met. For all quantitative output, consistent performance has been observed for all relevant subgroups including CT manufacturers, imaging parameter, patient sex and age as well as LAA morphology.

The segmentation output was compared with manually annotated data (i.e. ground truth) by calculating the dice score on the region of interest: the region of the left atrium containing the ostium and the main part of the left atrial appendage.

	Semi-automatic output	Fully automatic output
Mean dice score	0.98 ± 0.01	0.93 ± 0.04
Minimum Dice score	0.95	0.83
Maximum Dice score	0.99	0.97
Median Dice score	0.98	0.94

For TAVI, a study was performed on a cohort of 35 representative retrospective cases, during which quantitative outputs of FEops HEARTguide™ ALPACA were compared with manually annotated data (i.e. ground truth). The age of the studied cohort is 76.3±9.5y (48-91y), 46% were male subjects, and the aortic valve morphology was tricuspid in 74% of cases. Recent datasets representative for the intended population were used in this test cohort, covering different CT manufacturers, imaging parameters (e.g. slice thickness) and regions. No datasets were included that were used for training the AI models.

A performance goal was set for the perimeter-based diameter of the semi-automatically identified aortic annulus, as this is considered the most important landmark for the pre-operative planning of TAVI procedures. The maximum allowed difference in percentage must be less than the predetermined performance goal of ±10%. Please note that there is no automatically calculated perimeter-based diameter of the aortic annulus, as the algorithm only identifies the annular plane, and the measurement itself requires a manual action.

The Bland-Altman analysis conducted on the perimeter-based diameter of the aortic annulus provided the following results:

	Semi-automatic output
Mean of differences (%)	0.5 ± 1.9
Confidence interval (CI) on the mean (%)	(-0.1, 1.2)
Inferior Limit of Agreement (LoA) (%)	-3.2
Superior LoA (%)	4.2
CI on inferior LoA (%)	(-4.3, -2.1)
CI on superior LoA (%)	(3.1, 5.3)

The lower limit of the CI calculated on the inferior LoA (-4.3%) and the upper limit of the CI calculated on the superior LoA (5.3%) are within the maximum allowed difference of ±10%, so the performance goal has been met. For all quantitative output, consistent performance has been observed for all relevant subgroups including CT manufacturers, imaging parameter, patient sex and age as well as aortic valve morphology.

The segmentation output was compared with manually annotated data (i.e. ground truth) by calculating the dice score on the region of interest: the region of the aortic root, including the ascending aorta and the left ventricle.

	Semi-automatic output	Fully automatic output
Mean dice score	0.97 ± 0.01	0.96 ± 0.01
Minimum Dice score	0.92	0.92
Maximum Dice score	0.99	0.98
Median Dice score	0.97	0.96

SUMMARY

The characteristics that determine the functionality and performance of FEops HEARTguide™ ALPACA, the subject device, are substantially equivalent to the predicate device cleared under

K153736. The testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.