Hi-D Imaging AG
% Taras Bouzakine
Director, Regulatory Affairs
Veranex, Inc.
5420 Wade Park Blvd., Suite 204
Raleigh, North Carolina 27607

April 2, 2025

Re: K241984
Trade/Device Name: Hi-D Imaging 4TAVR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 24, 2025
Received: February 25, 2025

Dear Taras Bouzakine:

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241984

Device Name

Hi-D Imaging 4TAVR

Indications for Use *(Describe)*

Hi-D Imaging 4TAVR is a software as a medical device (SaMD) intended to support trained healthcare professionals (cardiologists, radiologists, clinical specialists) with the assessment of the cardiovascular anatomy and visualization and measurement of structures of the heart and vessels, including the aortic valve, and with pre-operational planning and sizing for transcatheter aortic valve replacement (TAVR) procedures by providing:
- Automatic segmentation of the full heart and vessels
- 3D and 2D rendering of DICOM images
- Automatic centerline detection
- Automatic detection of the LVOT (left ventricular outflow tract), aortic, sinus, sinotubular junction (STJ), ascending aorta and descending aorta planes
- Automatic multiplanar reconstruction (MPR) based on the centerline
- Measurement and visualization tools
- Manual measurement option for the user
- Automatic S-curve extraction
- Automatic report generation

Hi-D Imaging 4TAVR software is indicated for patients with tricuspid aortic stenosis who are eligible for TAVR operations and without any prior aortic valve implants.

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.

510(k) Notification K241984

GENERAL INFORMATION [807.92(a)(1)]

Applicant: Hi-D Imaging AG
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Date Prepared: February 24, 2025

DEVICE INFORMATION [807.92(A)(2)]

Classification: Class II per 21 CFR§892.2050, Medical image management and processing systems

Product Code: QIH, Automated Radiological Image Processing Software

Trade Name: Hi-D Imaging 4TAVR

Generic/Common Name: Automated Radiological Image Processing Software

PREDICATE DEVICE(S) [807.92(A)(3)]

3mensio Workstation (K153736)

DEVICE DESCRIPTION [807.92(A)(4)]

Hi-D Imaging 4TAVR ("the Device" or "4TAVR") is a cloud-based software as a medical device (SaMD) intended for use by healthcare professionals for the anatomy assessment of cardiac structures prior to Transcatheter Aortic Valve Replacement (TAVR) operations. 4TAVR enables healthcare professionals to maximize information using CT scan data and provide support for patient-specific pre-procedural planning of TAVR operations.

4TAVR utilizes an artificial intelligence (AI) deep learning model and computer vision methods that provide:

1) Fast and reliable automated analysis,
2) Fully automated segmentation of CT-based cardiac anatomy data,
3) 3D reconstruction and visualization of the anatomy, and
4) Fully automated report generation.

The main features of 4TAVR are:

- Fully automated extraction of heart components;
- Multiplanar reconstruction of the clinically-relevant anatomical planes for TAVR operations (i.e., left ventricular outflow tract (LVOT), annulus, sinus, sinotubular junction (STJ), ascending aorta, and descending aorta);
- 3D surface rendering of each heart component, including centerline detection;
- Fully automated detection and calculation of clinically relevant anatomical parameters such as annular perimeter, annular area, annular minimal and maximal diameter, LVOT diameter, ostium left main height and right coronary artery height, sinus of Valsalva, ascending and descending aorta perimeters, areas and diameters, sinotubular junction diameter and calcification for TAVR planning; and
- 3D downloadable meshes of aorta, left ventricle, left atrium, myocardium, right ventricle, calcium, and pulmonary artery.

4TAVR automatically processes DICOM images uploaded by the user and reports the results back to the user. The results include automatically generated measurements, 2D and 3D segmentation visualization, and a comprehensive report.

INDICATIONS FOR USE [807.92(a)(5)]

Hi-D Imaging 4TAVR is a software as a medical device (SaMD) intended to support trained healthcare professionals (cardiologists, radiologists, clinical specialists) with the assessment of the cardiovascular anatomy and visualization and measurement of structures of the heart and vessels, including the aortic valve, and with pre-operational planning and sizing for transcatheter aortic valve replacement (TAVR) procedures by providing:

- Automatic segmentation of the full heart and vessels
- 3D and 2D rendering of DICOM images
- Automatic centerline detection
- Automatic detection of the LVOT (left ventricular outflow tract), aortic, sinus, sinotubular junction (STJ), ascending aorta and descending aorta planes
- Automatic multiplanar reconstruction (MPR) based on the centerline
- Measurement and visualization tools
- Manual measurement option for the user
- Automatic S-curve extraction
- Automatic report generation

Hi-D Imaging 4TAVR software is indicated for patients with tricuspid aortic stenosis who are eligible for TAVR operations and without any prior aortic valve implants.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The technological characteristics of the Hi-D Imaging 4TAVR software device are substantially equivalent to the predicate device, 3mensio Workstation (K153736). Table 1 lists the regulatory information and technological characteristics of the subject and predicate devices. Any differences between the devices do not raise any new or different questions of safety or effectiveness.

Table 1: Summary of Technological Characteristics

Characteristics	Subject Device: Hi-Imaging 4TAVR	Predicate Device: 3mensio Workstation (K153736)
Regulatory Information		
Classification	21 CFR§892.2050 "Medical image management and processing systems"	21 CFR§892.2050 "Medical image management and processing systems"
Product Code	QIH (Automated Radiological Image Processing Software)	LLZ (System, Image Processing, Radiological)
Intended Use	Hi-D Imaging 4TAVR software is intended to visualize, analyze, and report anatomical structures of the full heart of the patient. Full heart comprises the components of the heart and vessels, including aorta, left ventricle, left atrium, myocardium, right ventricle, and pulmonary artery. The intended use is to support trained healthcare professionals (cardiologists, radiologists, and clinical specialists) before the cardiac operations, such as transcatheter aortic valve replacement (TAVR), in reading and interpreting medical DICOM images of the heart and vessels, and by measuring clinically relevant pre-procedural planning parameters (diameters, lengths, perimeters, areas). The software itself is not intended to be a decision-making tool by itself.	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 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)
Indications for Use	Hi-D Imaging 4TAVR is a software as a medical device (SaMD) intended to support trained healthcare professionals (cardiologists, radiologists, clinical specialists) with the assessment of the cardiovascular anatomy and visualization and measurement of structures of the heart and vessels, including the aortic valve, and with pre-operational planning and sizing for transcatheter aortic valve replacement (TAVR) procedures by providing: - Automatic segmentation of the full heart and vessels - 3D and 2D rendering of DICOM images - Automatic centerline detection - Automatic detection of the LVOT (left ventricular outflow tract), aortic, sinus, sinotubular junction (STJ), ascending aorta and descending aorta planes - Automatic multiplanar reconstruction (MPR) based on the centerline - Measurement and visualization tools - Manual measurement option for the user - Automatic S-curve extraction - Automatic report generation Hi-D Imaging 4TAVR software is indicated for patients with tricuspid aortic stenosis who are eligible for TAVR operations and without any prior aortic valve implants.	3mensio Workstation enables visualization and measurement of structures of the heart and vessels for: • Pre-operational 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: • Segmentation of cardiovascular structures • Automatic and manual center lumen line 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

Characteristics	Subject Device: Hi-Imaging 4TAVR	Predicate Device: 3mensio Workstation (K153736)
Technological Characteristics		
Input Data Type	CT data in DICOM format (vendor independent)	CT data in DICOM format (vendor independent)
Image Functionality	• Importing (Single and batch imports) • Encryption • History of processed images	• Exporting • Deleting • Anonymizing (no automatic deletion of original patient data) • Search
Centerline Extraction	• Automatic Centerline extraction for the entire aortic segment. • Automatic anatomical profiling of MPR planes along the aortic centerline.	• Realign orthogonal MPRs • Segmentation toolset: - Automatic segmentation of the ascending aorta - Automatic centerline (center lumen line) - Manual centerline - Centerline editing • Undo/redo operations • Volume sculpting
Image Assessments	• Automatic segmentation and anatomical measurements of heart components • Automatic anatomical measurements for pre-operational TAVR planning. • Automatic detection of TAVR anatomical landmarks. • TAVR sizing (IFU based TAVR sizing chart). • C-Arm angulation calculation (S-curve).	X-Ray Image Assessments: • Linear (length and diameter), angular and ROI measurements • Volume measurements • C-Arm angulation calculation • Text and arrow annotations • Calcium scoring for assessment of calcium in the aortic root • Calcium scoring for assessment of calcium in the coronary arteries • Segmentation and analysis of coronary artery tree centerline Intravascular ultrasound (IVUS) / optical coherence tomography (OCT) Image Assessments: • Orthogonal, oblique, double oblique, curved, cross-curved, stretched MPR rendering • MIP, AveIP, MinIP and color volume slabs • MIP volume rendering • Color volume rendering • Grayscale volume rendering • 2D slice review and stack comparison • 4D cine • Interactive VOI clipping • Multi-tissue color and opacity control • Active presets/User-defined presets

Characteristics	Subject Device: Hi-Imaging 4TAVR	Predicate Device: 3mensio Workstation (K153736)
Results Output	• 2D, 3D visuals with centerline • Downloadable 3D meshes of the heart compartments • Planes of interest visualized in 3D • Summary • Report generation, downloadable in PDF format • IFU based TAVR sizing chart	• Printout • Session state • PDF format • DICOM PDF report

SUBSTANTIAL EQUIVALENCE

The Hi-D Imaging 4TAVR is substantially equivalent to the predicate device, 3mensio Workstation (K153736). There are no differences in the technological characteristics between the devices which would raise any different questions of safety or effectiveness.

PERFORMANCE DATA [807.92(b)]

Software verification and validation testing was performed for the Hi-D Imaging 4TAVR in accordance with the FDA Guidance Document entitled, "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023. 4TAVR was verified at unit, integration, and system levels; and validated for accuracy, reproducibility, and usability. The acceptance criteria were established based on the type of testing, good software development practices, and literature review. All tests passed the acceptance criteria.

[807.92(b)(1)] Nonclinical Performance Data

Software Testing Summary:

Software verification testing was conducted at the unit, integration, and system levels and confirms that the Hi-D Imaging 4TAVR meets the software/system requirements. The acceptance criteria were set based on good software development practices, to pass all the scenarios (100%) in the unit, integration, and system levels. All the nonclinical tests passed the acceptance criteria. The collective results of conducted software testing demonstrate that the design of the Hi-D Imaging 4TAVR meet the established specifications necessary for consistent performance during its intended use. In addition, the collective software testing demonstrates that the Hi-D Imaging 4TAVR does not raise different questions of safety or effectiveness when compared to the predicate device.

Reproducibility Testing Summary:

The reproducibility of 4TAVR was analyzed by tests. Randomly selected 100 cases from three U.S. sites were run twice using 4TAVR.

In one investigation, the automatically segmented heart components were compared pixel-by-pixel within 100 U.S. cases. The acceptance criteria were set to be 99.99% identical pixels of the segmented volumes. All the tests have passed the acceptance criteria.

In the second investigation, the reports of the same 100 cases generated by 4TAVR software were compared (in mm and mm2). The acceptance criteria were set to be 99.99% identical values in both reports for all 100 cases. The tests showed 100% reproducibility and hence have passed the acceptance criteria.

The results of the reproducibility testing demonstrate that the automatically segmented volumes and the report measurements are reproducible.

Usability Testing Summary:

The usability of 4TAVR was tested by Human Factor Engineering studies. The summative studies were performed with 15 users that were eligible for the intended user description. The users were given 7 scenarios each (105 scenarios in total) and were accompanied by an observer and a moderator during the process. The acceptance criteria were set to observe 0% user errors and to have 95% of the scenarios to be passed with no difficulty. The usability tests passed the acceptance criteria by showing 0% use error and 98% of the cases passed without difficulty.

The results of the usability studies show that 4TAVR can be used effectively by the users without any error.

[807.92(b)(2)] Clinical Performance Data

Accuracy Testing Summary:

Clinical testing was not relied upon to demonstrate substantial equivalence of Hi-D Imaging 4TAVR to the predicate device.

Technical (clinical) validation testing aimed at demonstrating the performance of Hi-D Imaging 4TAVR was conducted in five (5) separate studies encompassing a total of 929 CT scans of patients that are TAVR-eligible without any previously implanted medical device at aortic position. The accuracy tests focused on comparing the manually performed ground truth measurements by experts and the automatically generated measurements of 4TAVR.

Commercially available FDA-cleared and CE-Marked software were used by the ground truth readers, including the predicate device. It was ensured that the ground truth readers have relevant clinical experience and follow clinical guidelines for the measurements. The acceptance criteria were established by a combination of literature review and calculating the difference between reader measurements in the five (5) technical validation testing. The acceptance criteria were set to be >90% accuracy for annulus parameters, and >85% accuracy for other TAVR parameters between 4TAVR results and the mean of observers' ground truth measurements.

Three of these studies were conducted in the U.S. totaling 289 CT scans, and two studies were conducted in Europe totaling 640 CT scans. In the U.S. studies, the percentage agreement with the ground truth data in all annulus parameters were >98%. In Europe studies, the percentage agreement with the ground truth data in all annulus parameters were >97%.