July 20, 2026

Hi-D Imaging AG
Utku Gulan
CEO
Technoparkstrasse 2
Winterthur, 8406
Switzerland

Re: K261535
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: June 19, 2026
Received: June 22, 2026

Dear Utku Gulan:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261535

Please provide the device trade name(s).

Hi-D Imaging 4TAVR

Please provide your Indications for Use below.

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 femoral arteries, and with pre-procedural 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 detection of abdominal aorta, left and right common iliac, left and right external iliac, left and right femoral artery 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

510(k) Notification K261535

GENERAL INFORMATION [807.92(a)(1)]

Applicant: Hi-D Imaging AG
Technoparkstrasse 2
Winterthur 8406, Switzerland
Phone: +41 52 213 1919

Contact Person: **Utku Gülan**
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Winterthur 8406, Switzerland
Phone: +41 52 213 1919
Email: utkugulan@hidimaging.com

Date Prepared: July 20, 2026

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)]

Hi-D Imaging 4TAVR v1.14.1_a (K241984)

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 pre-procedural TAVR analysis,
2) Fully automated segmentation of CT-based cardiac anatomy data,
3) 3D reconstruction and visualization of the heart anatomy, and

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4) Fully automated TAVR 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, descending aorta, abdominal aorta, left and right femoral artery, left and right common iliac artery, and left and right external iliac artery);
- 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, annular mean 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, calcification, minimum diameter of abdominal artery, minimum diameter of left and right common iliac artery, minimum diameter of left and right external iliac artery, minimum diameter of left and right femoral artery, and tortuosity of left and right femoral artery for TAVR planning; and
- 3D downloadable meshes of aorta, left ventricle, left atrium, myocardium, right ventricle, calcium, pulmonary artery, abdominal aorta, left and right femoral artery, left and right common iliac artery, and left and right external iliac 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 TAVR 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 femoral arteries, and with pre-procedural 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 detection of abdominal aorta, left and right common iliac, left and right external iliac, left and right femoral artery 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;

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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, Hi-D Imaging 4TAVR v1.14.1_a (K241984). 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 (v1.15.0_a)	Predicate Device: Hi-D Imaging 4TAVR (K241984)
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)	QIH (Automated Radiological Image Processing Software)
Intended Use	Hi-D Imaging 4TAVR software is intended to visualize, analyze, and report anatomical structures of the full heart and femoral arteries 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.	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.
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	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

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Characteristics	Subject Device: Hi-Imaging 4TAVR (v1.15.0_a)	Predicate Device: Hi-D Imaging 4TAVR (K241984)
	the heart and vessels, including the aortic valve and femoral arteries, and with pre-procedural 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 detection of abdominal aorta, left and right common iliac, left and right external iliac, left and right femoral artery 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.	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.
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	• Importing (Single and batch imports) • Encryption • History of processed images
Centerline Extraction	• Automatic Centerline extraction for the entire aortic segment and femoral segments. • Automatic anatomical profiling of MPR planes along the aortic and femoral centerline.	• Automatic Centerline extraction for the entire aortic segment. • Automatic anatomical profiling of MPR planes along the aortic centerline.
Image Assessments	• Automatic segmentation and anatomical measurements of heart components • Automatic anatomical measurements for pre-operational TAVR planning.	• Automatic segmentation and anatomical measurements of heart components • Automatic anatomical measurements for pre-operational TAVR planning.

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Characteristics	Subject Device: Hi-Imaging 4TAVR (v1.15.0_a)	Predicate Device: Hi-D Imaging 4TAVR (K241984)
	• Automatic detection of TAVR anatomical landmarks. • TAVR sizing (IFU based TAVR sizing chart). • C-Arm angulation calculation (S-curve).	• Automatic detection of TAVR anatomical landmarks. • TAVR sizing (IFU based TAVR sizing chart). • C-Arm angulation calculation (S-curve).
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	• 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

SUBSTANTIAL EQUIVALENCE

The Hi-D Imaging 4TAVR v.1.15.0_a is substantially equivalent to the predicate device, Hi-D Imaging 4TAVR (K241984). 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 (v1.15.0_a) in accordance with the FDA Guidance Document entitled, "Content of Premarket Submissions for Device Software Functions," issued on June 14, 2023. The device was verified at unit, integration, and system levels; and validated for accuracy and reproducibility. The acceptance criteria were established based on the type of testing, good software development practices, and literature review. The tests passed the acceptance criteria.

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

Software Testing Summary:

Software verification testing conducted at the unit, integration, and system levels confirms that the Hi-D Imaging 4TAVR v1.15.0_a meets the software/system requirements. The acceptance criteria were set based on good software development practices in the unit, integration, and system levels. The collective results of conducted software testing demonstrate that the design of the Hi-D Imaging 4TAVR v1.15.0_a 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 v1.15.0_a does not raise different questions of safety or effectiveness when compared to the predicate device.

Reproducibility Testing Summary:

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The reproducibility of the device was tested by two investigations. Randomly selected 80 cases from 7 sites U.S. and Europe were run 3 times using the device.

In one investigation, the automatically segmented heart components were compared pixel-by-pixel within 80 U.S. cases. The acceptance criteria were set to compare pixels of the segmented compartments requiring 99.9% identical pixels of the segmented volumes. All of the tests have passed the acceptance criteria.

In the second investigation, the reports of the same 80 cases were compared based on the measurements (in mm and mm2) of the aortic and LVOT planes. The acceptance criteria were set to compare values for all three reports, requiring 99.9% identical results across all 80 cases. The tests have passed the acceptance criteria.

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

Usability Testing Summary:

The usability testing has not been re-performed as the usability of the device largely remains the same as the Predicate device. The usability tests on the predicate device showed that the device can be used effectively by 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 v1.15.0_a to the predicate device.

Technical (clinical) validation testing aimed at demonstrating the performance of Hi-D Imaging 4TAVR v1.15.0_a was conducted in 3 independent studies encompassing a total of 289 CT scans of aortic stenosis patients eligible for the TAVR operations for the aortic root validation and 2 independent studies encompassing a total of 85 CT scans of aortic stenosis patients eligible for the TAVT operations for the vascular access validation. The accuracy tests included comparing the manually performed ground truth measurements (multiplanar reconstruction and plane determination) and the automatically generated measurements of the device. Commercially available FDA-cleared and CE-Marked software were used for human expert measurements. 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 interobserver variabilities in the studies.

All these studies were conducted with the U.S. patient cohorts in the U.S. hospitals totaling 289 CT scans for the root and 85 CT scans for the vascular access validation. All annulus parameters have >97% agreement (mean difference percentage is <3%). All annulus parameters show a high correlation of above 0.92 with the ground truth measurements (except for annulus minor diameter with a correlation of 0.87 and eccentricity with a correlation of 0.6 for which we observe high inter-observer variability in the experts' human measurements).

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The global minimum iliofemoral diameters for both left and right access have a >92% agreement (mean difference percentage is <7%) with a mean difference below 0.55 mm. 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. All of the accuracy measurements have passed the acceptance criteria. The combined results from validation studies demonstrate that the fully automated Hi-D Imaging 4TAVR v1.15.0_a planning software can be effectively used for pre-operational planning.

CONCLUSIONS [807.92(b)(3)]

The subject device Hi-D Imaging 4TAVR v.1.15.0_a is substantially equivalent to the predicate device Hi-D Imaging 4TAVR v1.14.1_a (K241984).

Based on the results from the software verification and validation testing performed in support of the new Hi-D Imaging 4TAVR device, it is concluded that the device is safe, effective, and performs at least as safely and effectively as the legally marketed predicate device.