Keya Medical Technology Co., Ltd.
% Kelliann Payne
Partner
Hogan Lovells
1735 Market St., Suite 2300
Philadelphia, Pennsylvania 19103

June 4, 2025

Re: K260497
Trade/Device Name: DEEPVESSEL Plaque
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 6, 2026
Received: May 6, 2026

Dear Kelliann Payne:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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.	K260497

Please provide the device trade name(s).

DEEPVESSEL Plaque

Please provide your Indications for Use below.

DEEPVESSEL Plaque is a coronary analysis software developed for the analysis of Computed Tomography Angiography (CTA) DICOM data for patients aged 22 and above with suspected or known coronary artery disease (CAD). It provides presence and extent of coronary plaques and stenosis in patients who underwent CCTA for evaluation of suspected or known CAD.

Users should be aware that certain views make use of interpolated data. This is data that is created by software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

The results of the analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. DEEPVESSEL Plaque results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment. The software is not intended to replace the skill and judgement of a qualified medical practitioner and should only be used by people who have been appropriately trained to use the software.

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
KEYA MEDICAL'S DEEPVESSEL PLAQUE
K260497

Submitter

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Date of Preparation: June 4, 2026

Name of Device: DEEPVESSEL Plaque

Classification Name: Radiological Image Processing System

Regulatory Class: Class II

Product Code: QIH

Regulation: 21 CFR §892.2050

Predicate Device: Autoplaque 3.0 (K212758, Cedars-Sinai Medical Center)

Device Description

DEEPVESSEL Plaque ("DVPlaque", the subject device) is a web-based image analysis application for the purpose of characterizing and quantifying plaque and stenosis in coronary arteries based on previously acquired CCTA DICOM data.

DVPlaque applies deep learning neural networks to segment coronary arteries, lumen and vessel walls, which will be reviewed and edited by trained and qualified analysts, if needed. Plaque, stenosis, and vessel measurements are outputted based on the analyst-editable segmentation, utilizing simple rule-based mathematical calculation.

DVPlaque provides a visualization of DVPlaque analysis in two reports — Cardisight Overview Report and Plaque Analysis Report. In Cardisight Overview Report, location and CAD-RADS stenosis category of the plaque are visually over-viewed in a simplified 2D model if stenosis and plaque exist.

In Plaque Analysis Report, quantitative characteristics of the plaque, including total plaque volume, calcified plaque (CP) volume, non-calcified plaque (NCP) volume, low-density plaque (LDP) volume, and plaque burden (defined as percent plaque volume and calculated as total plaque volume/vessel volume) are outputted both on main vessel branch level and on patient level.

Reports of DVPlaque are provided to clinicians to enable them to assess the presence and extent of coronary plaque, aiding in determining treatment paths. These reports are not intended to be the final report used in patient diagnosis and treatment, and should be reviewed with other clinical information. Clinicians may request a re-analysis of the CCTA DICOM data if they do not agree with the report analyses.

Intended Use / Indications for Use

DEEPVESSEL Plaque is a coronary analysis software developed for the analysis of Computed Tomography Angiography (CTA) DICOM data for patients aged 22 and above with suspected or known coronary artery disease (CAD). It provides presence and extent of coronary plaques and stenosis in patients who underwent CCTA for evaluation of suspected or known CAD.

Users should be aware that certain views make use of interpolated data. This is data that is created by software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

The results of the analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. DEEPVESSEL Plaque results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment. The software is not intended to replace the skill and judgement of a qualified medical practitioner and should only be used by people who have been appropriately trained to use the software.

Comparison to the Predicate Device

The overall intended use for DEEPVESSEL Plaque is the same as the predicate device: both devices are intended to process radiological images and provide measurements of anatomical components in those images. Furthermore, the subject device's indications for use statement is similar to the predicate device. Both devices are indicated to provide an optimized non-invasive application to analyze coronary anatomy and pathology from CT angiographic images, to provide a post-processing tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques and luminal stenosis, and to provide analysis results to aid in the determination of treatment paths by the healthcare professional, in conjunction with other patient data. Additionally, both devices are indicated for use by trained operators.

The differences in indications for use between the subject device and predicate device do not cause the subject device to have a different overall intended use. In particular, the location of use for the software operator differs, as DEEPVESSEL Plaque is indicated as a web-based application that can be operated off-site with imaging data transmitted via web-based software, while the predicate device is indicated as a workstation- based desktop device for use at clinical sites. However, for both devices the final analysis results are indicated to be provided to a healthcare professional for use at a clinical location. Therefore, the indicated recipients and locations of application of the final device output are the same for both devices. Of note, the location of use and workflow of the DEEPVESSEL Plaque software is the same as the reference device – i.e., trained operators located in regional data centers use the software device to perform an analysis and generate a report that is subsequently provided to a healthcare professional end user.

Comparison of Technological Characteristics

The technology of DEEPVESSEL Plaque is similar to the predicate device (see **Table 1**). Both devices analyze CT angiographic images for the presence and extent of coronary plaque and luminal stenosis. In addition, they both require trained operators to perform the assessment. Both devices utilize deep learning-based vessel, plaque and lumen segmentation, which is reviewed and can be edited, if necessary, by the operators. Both devices provide equivalent quantitative measurements in a report to the healthcare professional after completing the analysis. These reports are intended to be reviewed by the healthcare professional and used in conjunction with other patient information, such as the original CT images, clinical history, symptoms, clinical risk factors, results of other diagnostic tests, and the clinical judgement of the ordering prescriber. Both devices have demonstrated agreement between clinical expert readers and software measurements in clinical performance testing and have demonstrated appropriate inter-operator and intra-operator agreement.

There are two key technological differences between the subject device and the predicate. First, the location of the DICOM image data processing is different: The DEEPVESSEL Plaque Cloud software is web-based and receives DICOM images via transmittal by a secure picture archiving and communication system (PACS), while the AutoPlaque predicate software resides on a commercial computer platform at the clinical site and receives DICOM image data via loading from the local computer hard drive. Second, the location of the trained software operator may be different: The subject device operator can be at a remote site, while the predicate device operator is at the clinical site on a desktop computer. For both devices, the software operators are trained to review anatomy, define and correct the vessels of interest and generate a report. Both devices allow the end user to revise the analysis as needed, but the approach differs: with AutoPlaque, the user can directly repeat or modify the analysis on-site; with DEEPVESSEL Plaque, the user can request the remote operator to perform a re-analysis.

Therefore, the minor technological differences between the subject and predicate device do not raise different questions of safety or effectiveness.

Table 1. Technology Comparison to Predicate

Parameter	Subject Device: DEEPVESSEL Plaque	Proposed Predicate Device: Autoplaque 3.0 (K212758)	Comments
Computer Operating System	Client-Server Google Chrome Application	Windows OS Mac OS	Substantially similar. The difference in platform does not impact safety or effectiveness of the device.
Stand-alone software	Yes	Yes	Same
DICOM Compliance	DICOM 3.0 Compliant (or higher)	DICOM 3.1 Compliant (or higher)	Substantially similar. The difference in platform does not impact safety or effectiveness of the device.
2D Imaging	Review of coronary vessels in 2D Multi-Planar Reconstruction (MPR), Curved planar reformation (CPR), and Straightened Curved Planar Reformation (sCPR)	Review of coronary vessels in 2D MPR, curved MPR, and straightened view	Same. The difference is in the nomenclature only.
2D Measurement	2D measurement tools of vessel diameter and contour.	2D measurement tools of vessel diameter and contour	Same
3D Imaging	Yes	Review of structures in 3D	Same. The difference is in the nomenclature only.
Maximum intensity projection (MIP)	No	Yes	This visualization method is not necessary analyzing the presence and extent of coronary plaque and luminal stenosis. The difference in platform does not impact safety or effectiveness of the

Parameter	Subject Device: DEEPVESSEL Plaque	Proposed Predicate Device: Autoplaque 3.0 (K212758)	Comments
			device.
Multiplanar reformatting (MPR): MPR with oblique slicing and variable slab thickness	No	Yes	This is not necessary analyzing the presence and extent of coronary plaque and luminal stenosis.
Volume rendering based on centerlines	Yes	No	A preprocessing method that modifies the lumen boundary, with no impact on product efficacy or safety.
SCCT Segment Naming	Yes (user edit)	Yes (user edit)	Same
Automatic/Semi-automatic lumen boundary determination	Yes (user edit)	Yes (user edit)	Same
Visualize plaque information	Yes (user edit)	Yes (user edit)	Same
Ideal Model Adjustment	Yes	No	A graphical representation based on plaque information that does not affect product efficacy or safety.
Graphic and text results	Yes	Yes	Same
Quantitative Measurements			
Vessel, plaque, and lumen segmentation	Yes	Yes	Same
Total Plaque Volume	Yes	Yes	Same
Calcified Plaque Volume	Yes	Yes	Same
NCP volume: noncalcified plaque volume	Yes	Yes	Same

Parameter	Subject Device: DEEPVESSEL Plaque	Proposed Predicate Device: Autoplaque 3.0 (K212758)	Comments
LD-NCP volume: low-density noncalcified plaque volume	Yes	Yes	Same
Vessel Volume	No	Yes	This difference does not impact safety or effectiveness of the device.
NCP burden: noncalcified plaque volume / analyzed vessel volume	Yes	Yes	Same
LD-NCP burden: low-density noncalcified plaque volume / analyzed vessel volume	Yes	Yes	Same
CP burden: calcified plaque volume / analyzed vessel volume	Yes	Yes	Same
Total plaque burden: total plaque volume / analyzed vessel volume	Yes	Yes	Same
Plaque composition NCP: noncalcified plaque composition (NCP volume / total plaque volume)	No	Yes	This difference does not impact safety or effectiveness of the device.
Plaque composition CP: calcified plaque composition (CP volume / total plaque volume)	No	Yes	This difference does not impact safety or effectiveness of the device.
Plaque composition LDNCP: low-density noncalcified plaque	No	Yes	This difference does not impact safety or effectiveness of the device.

Parameter	Subject Device: DEEPVESSEL Plaque	Proposed Predicate Device: Autoplaque 3.0 (K212758)	Comments
composition (LD-NCP volume / NCP volume)			
Diameter stenosis: Maximum diameter stenosis, with respect to proximal and distal references	Yes	Yes	Same
QCAD: Maximum diameter stenosis	Yes	Yes	Same
Remodeling index: ratio of maximum vessel area / proximal and distal references	No	Yes	This difference does not impact safety or effectiveness of the device.
Area stenosis: maximum area stenosis, with respect to proximal and distal references	No	Yes	This difference does not impact safety or effectiveness of the device.
Plaque length: diseased vessel length	No	Yes	This difference does not impact safety or effectiveness of the device.
Contrast density difference: maximum difference in contrast density over lesion with respect to proximal	No	Yes	This difference does not impact safety or effectiveness of the device.
MLD: minimal luminal dimeter over lesion	Yes	Yes	Same
MLA: minimum luminal area over lesion	No	Yes	This difference does not impact safety or effectiveness of the device.

Parameter	Subject Device: DEEPVESSEL Plaque	Proposed Predicate Device: Autoplaque 3.0 (K212758)	Comments
Vessel profile: Area, maximum diameter, minimum diameter measured from selected vessel cross section	No	Yes	This difference does not impact safety or effectiveness of the device.
Lumen profile: Area, maximum diameter, minimum diameter measured from selected lumen cross section	No	Yes	This difference does not impact safety or effectiveness of the device.

Performance Testing

The 510(k) submission provided performance data to establish the substantial equivalence of DVPlaque to the predicate device. A summary of these performance tests is provided below.

Software Verification and Validation:

Software verification and validation testing were conducted to demonstrate that the subject device meets specifications and works as intended. This included algorithm unit testing, algorithm integration testing, full system testing, and service portal integration testing.

Reproducibility/Repeatability Evaluations:

Reproducibility & Repeatability (R&R) testing was performed on a group of CT scans with diverse disease conditions to evaluate the variation of repeated analyses of DEEPVESSEL Plaque with different image analysts (reproducibility) at different days with a washout-period in between to avoid memory effects (repeatability). The R&R dataset represented included varying plaque volumes, plaque compositions, and stenosis grades 0 through 4. The R&R cases included a total of 23 subjects with a mean age of 62.2 years. Cases came from the same three U.S. clinical institutions used for validation, and scans represented GE, Arineta, Toshiba, and Siemens CT manufacturers. Testing results met the pre-specified variability metric threshold and thus demonstrated acceptable performance. See **Table 2** below.

Table 2. Summary of Repeatability and Reproducibility Testing

Endpoint	Factor	Acceptance Criterion	Pass/Fail
Total Plaque Volume	Day	%CV due to Day ≤ 5.0%	Pass
Total Plaque Volume	Analyst	%CV due to Analyst ≤ 5.0%	Pass
Vessel Volume	Day	%CV due to Day ≤ 5.0%	Pass
Vessel Volume	Analyst	%CV due to Analyst ≤ 5.0%	Pass

Clinical Validation Study:

A retrospective, multi-center clinical validation study was conducted to evaluate the performance of the DEEPVESSEL Plaque software for the detection, quantification, and characterization of coronary atherosclerotic plaque and stenosis using coronary computed tomography angiography (CCTA).

The clinical validation study included a total of 147 CCTA datasets collected from three independent U.S. clinical sites.

The 147 subjects included in the study ranged from 22 to 88 years old and included 91 men and 56 women. Ethnicity information was collected with 72 White (49.0%), 35 Hispanic (23.8%), 22 Asian (15.0%), 4 Black (2.7%), 1 others (0.7%) and unknown 13 (8.8%). The validation cohort also represented a broad range of coronary disease severity, with patient-level CAD-RADS categories spanning CAD-RADS 0-5, including 61 subjects (41.5%) with clinically significant stenosis (CAD-RADS ≥3). In addition, all major plaque subtypes were represented in the dataset, including calcified plaque (130 subjects; 88.4%), non-calcified plaque (134 subjects; 91.2%), and low-density plaque (133 subjects; 90.5%).

Each subject contributed one CCTA image dataset. Accordingly, vessel-level analyses were performed on 441 coronary vessel territories, consisting of the left main plus left anterior descending artery (LM+LAD), left circumflex artery (LCX), and right coronary artery (RCA) for each subject, and plaque-level analyses evaluated 711 DVPlaque-detected plaques against expert-reader ground-truth plaques in the primary plaque-detection analysis. CCTA studies were acquired using ≥64–detector row CT scanners from multiple manufacturers, including GE, Toshiba, Arineta, and Siemens, representing a range of scanner models and imaging parameters.

Performance of DEEPVESSEL Plaque was evaluated against a reference standard established by consensus of three expert readers. Two expert readers independently reviewed each case and

provided measurements of plaque volume, plaque composition, vessel and lumen volumes, and CAD-RADS stenosis category. The third senior expert reader adjudicated discrepancies according to predefined study rules to establish the final consensus truth. This consensus served as the ground truth for all analyses.

The pivotal clinical validation dataset was independent from the development dataset. The development and validation datasets were separated by site, with development data comprising CCTA images from 1,200 patients acquired from five medical centers in China and one medical center in Europe, while the pivotal validation dataset was collected from three U.S. clinical sites. The protocol also excluded data previously analyzed by DVPlaque. DVPlaque analysts and expert readers were blinded to each other's results during validation.

Clinical performance evaluation demonstrated strong agreement between DEEPVESSEL Plaque and the reference standard for quantitative plaque measurements and stenosis assessment. Correlation analyses showed high agreement for total plaque volume, calcified and non-calcified plaque volumes, vessel volume, and lumen volume at both the patient and vessel levels. Agreement for CAD-RADS stenosis category demonstrated substantial concordance with expert assessment. The results are summarized in **Table 3**. All performance testing results met pre-defined acceptance criteria.

Subgroup analyses demonstrated consistent performance across coronary vessel territories, stenosis severity categories, scanner manufacturers, imaging parameters, and patient demographics, indicating robust and generalizable performance across a clinically representative population.

Table 3. Key Endpoints and Performance of DVPlaque

Performance Metric (Per-Patient)	Statistic	Results	Pass/Fail
Total Plaque Volume	Pearson Correlation Coefficient	0.976	Pass
Calcified Plaque Volume	Pearson Correlation Coefficient	0.994	Pass
Non-calcified Plaque Volume	Pearson Correlation Coefficient	0.945	Pass
Vessel Volume	Pearson Correlation Coefficient	0.985	Pass
Plaque Burden	Pearson Correlation Coefficient	0.978	Pass
Stenosis Category	Weighted Kappa	0.810	Pass
Vessel Segmentation	Dice coefficient	0.888	Pass
Lumen Segmentation	Dice coefficient	0.887	Pass

Conclusion

The information provided above supports that DEEPVESSEL Plaque is as safe and effective as the predicate device. The device has the same intended use as the predicate device, and minor differences in indications for use do not alter the intended use of the device and do not affect its safety and effectiveness. In addition, the minor technological differences between the devices do not raise different questions of safety or effectiveness, and they are addressed through software verification and validation testing and a clinical validation study. Therefore, DEEPVESSEL Plaque is substantially equivalent to the predicate device.