Cedars-Sinai Medical Center
℅ Philip Won
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street NW, Suite 1200
WASHINGTON DC 20005

May 19, 2023

Re: K212758
Trade/Device Name: Autoplaque 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 24, 2023
Received: April 25, 2023

Dear Philip Won:

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
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: 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)*
K212758

Device Name
Autoplaque 3.0

Indications for Use *(Describe)*
Autoplaque is intended to provide an optimized non-invasive application to analyze coronary anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Autoplaque is a workstation-based post processing application. It is a non-invasive diagnostic reading software intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques and luminal stenoses.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the 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.

Autoplaque must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.

Typical users of Autoplaque are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

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) SUMMARY

Cedars-Sinai Medical Center's Autoplaque 3.0

In accordance with 21 CFR § 807.92 the following summary of information is provided:

I. Submitter

Cedars-Sinai Medical Center
8700 Beverly Blvd.
Los Angeles, CA 90048

Contact Person: Damini Dey, Ph.D.
Title: Director, Quantitative Image Analysis Program, Biomedical Imaging Research Institute (BIRI), Department of Biomedical Sciences, Cedars Sinai Medical Center Cedars-Sinai Medical Center
Phone: 310-423-1517
Fax: 310-423-8396

II. Date of 510(k) Summary Preparation:

May 2, 2023

III. Device

Device Proprietary Name:	Autoplaque 3.0
Common or Usual Name:	Image Processing System, Radiological
Classification Name:	Automated Radiological Image Processing Software Radiological Imaging Processing System
Regulation Number:	21 CFR § 892.2050
Product Code:	QIH, LLZ
Device Classification	II

IV. Predicate Device

Primary Predicate Device:

- Autoplaque add-on ORS Visual, K122429, Object Research Systems (ORS) Inc.

V. Device Description

Autoplaque 3.0, a stand-alone software, performs post-processing of coronary Computed Tomography Angiography (CTA) images and measurements of components of images using computerized algorithms.

Autoplaque 3.0 aids the physician with measurement of coronary artery stenosis and provides measurements for coronary plaque and coronary artery remodeling. Autoplaque 3.0 does not replace standard clinical practice or clinician decision making.

Autoplaque 3.0 allows for standardized characterization of plaque and stenosis from DICOM image data (loaded from the local computer hard drive) and includes the following features:

- Review of heart and coronary vessels in Multiplanar Reformatting (MPR), curved MPR, and straightened MPR views;
- Measurement of vessel diameter and area;
- Characterization and measurement of plaque parameters; and
- Measurement of lumen diameter, area, and luminal stenosis.

Autoplaque 3.0 includes automated vessel, plaque and lumen segmentation, which is reviewed and can be edited, if necessary, by the clinician.

Autoplaque 3.0 can run on Windows or Mac computer platforms. The minimum hardware specifications are specified in the user manual.

VI. Indications for Use

Autoplaque is intended to provide an optimized non-invasive application to analyze coronary anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.

Autoplaque is a workstation-based post processing application. It is a non-invasive diagnostic reading software intended for use by cardiologists and radiologists as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques and luminal stenoses.

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations. Users should be aware that certain views make use of interpolated data. This is data that is created by the 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.

Autoplaque must be installed on a suitable commercial computer platform. It is the user's responsibility to ensure the monitor quality and ambient light conditions are consistent with the clinical applications.

Typical users of Autoplaque are trained medical professionals, including but not limited to radiologists, clinicians, technologists, and others.

VII. Comparison of Technological Characteristics

Autoplaque 3.0 and the predicate device are identical with respect to intended use and technological characteristics with the exception of the following:

- Compatibility of the subject device with Mac operating system (OS);
- Provision of the subject device as stand-alone software versus an add-on; and
- Deep learning-based vessel, plaque and lumen segmentation, which is reviewed and can be edited, if necessary, by the clinician.

The table below compares the key technological features between the subject and predicate devices.

Parameter	**Subject Device: Autoplaque 3.0 (K212758)**	**Predicate Device: Autoplaque add-on ORS Visual (K122429)**
Computer operating system	Windows OS Mac OS	Windows OS only
Stand-alone software	Yes	No, ORS Visual add-on
DICOM compliance	DICOM 3.1	Same
2D Imaging	Review of coronary vessels in 2D MPR, curved MPR, and straightened view.	Same
2D Measurement	2D measurement tools of vessel diameter and contour	Same
3D Imaging	Review of structures in 3D	Same
Maximum intensity projection (MIP)	MIP with interactive control	Same
Multiplanar reformatting (MPR)	MPR with oblique slicing and variable slab thickness	Same
Quantitative Measurements		
NCP volume: non-calcified plaque volume	Yes	Same
CP volume: calcified plaque volume	Yes	Same
LD-NCP volume: low-density noncalcified plaque volume	Yes	Same
Total plaque volume	Yes	Same
Vessel volume	Yes	Same

Parameter	Subject Device: Autoplaque 3.0 (K212758)	Predicate Device: Autoplaque add-on ORS Visual (K122429)
NCP burden: noncalcified plaque volume/analyzed vessel volume	Yes	Same
LD-NCP burden: low-density noncalcified plaque volume/analyzed vessel volume	Yes	Same
CP burden: calcified plaque volume/analyzed vessel volume	Yes	Same
Total plaque burden: total plaque volume/analyzed vessel volume	Yes	Same
Plaque composition NCP: Noncalcified plaque composition (NCP volume /total plaque volume)	Yes	Same
Plaque composition CP: Calcified plaque composition (CP volume/total plaque volume)	Yes	Same
Plaque composition LD-NCP: low-density noncalcified plaque composition (LD-NCP volume/ NCP volume)	Yes	Same
Diameter stenosis: maximal diameter stenosis, with respect to proximal and distal references	Yes	Same
QCAD: Maximal diameter stenosis, with respect to proximal and distal references	Yes	Same
Remodeling index: ratio of maximum vessel area/proximal and distal references	Yes	Same
Area stenosis: maximum area stenosis, with respect to proximal and distal references	Yes	Same
Plaque length: diseased vessel length	Yes	Same
Contrast density difference: maximum difference in contrast density over lesion with respect to proximal	Yes	Same
MLD: minimal luminal dimeter over lesion	Yes	Same

Parameter	Subject Device: Autoplaque 3.0 (K212758)	Predicate Device: Autoplaque add-on ORS Visual (K122429)
MLA: minimum luminal area over lesion	Yes	Same
Vessel profile: Area, maximum diameter, minimum diameter measured from selected vessel cross section	Yes	Same
Lumen profile: Area, maximum diameter, minimum diameter measured from selected lumen cross section	Yes	Same
Vessel, plaque, and lumen segmentation	Deep learning based, validated with ground truth by clinician expert readers, with full option to edit.	Algorithm based, validated with ground truth by clinician expert readers, with full option to edit.

Discussion: As shown above, there are slight technological differences between the subject and predicate devices with respect to computer operating system, provision of the product as stand-alone software, and vessel, plaque, and lumen segmentation method; however, these differences do not raise new questions of safety and effectiveness, and the differences are addressed through software verification and validation as well as clinical performance studies.

VIII. Performance Data

Software verification and validation were conducted on the subject device to demonstrate that the subject device meets specifications and works as intended.

In addition, clinical validation studies were undertaken to verify and validate that Autoplaque 3.0 performs as intended. A summary of these studies is provided below.

1. Comparison with Expert Reader Measurements in a Multicenter US Patient Population

Performance data was collected on a data set of clinically indicated coronary computed tomography angiography (CCTA) images from multiple U.S. sites. The patient population consisted of 201 patients (53% men, 47% women) with a mean age of 60 ± 12 years. A total of 781 lesions from 201 patients were analyzed. Ethnicity available in 80 patients was as follows: White alone (not Hispanic or Latino) 18%, Black 19%, Hispanic or Latino 61%, and American Indian and Alaska native alone 1%. The CT scanners to collect images included commercial CT scanners from Siemens, Philips and GE. Ground truthing was performed by a board-certified imaging cardiologist. This study established concordance and agreement between clinician expert reader and Autoplaque 3.0 measurements for total plaque volume, calcified plaque volume, non-calcified plaque volume, and diameter stenosis using the acceptance criteria of an intraclass correlation coefficient and correlation coefficient. An excellent agreement was

shown between the subject device and expert reader measurements for total plaque volume, noncalcified plaque volume, calcified plaque volume, and diameter stenosis.

2. Comparison with Expert Reader Measurements in a Non-US Patient Population

Performance data was collected on clinically indicated coronary computed tomography angiography (CCTA) images from multiple non-U.S. external sites. The patient population consisted of 175 patients (53% men, 47% women) with a mean age of age 56 ± 9 years. A total of 1081 lesions from 175 patients were analyzed. The CT scanners to collect images included commercial CT scanners from Siemens, Philips and Canon. Ground truthing was performed by two cardiologists with one additional highly experienced radiologist to resolve discrepancies. This study established concordance and agreement between clinician expert reader and Autoplaque 3.0 measurements for total plaque volume, calcified plaque volume, non-calcified plaque volume, and diameter stenosis using the acceptance criteria of an intraclass correlation coefficient and correlation coefficient. An excellent agreement was shown between the subject device and expert reader measurements for total plaque volume, noncalcified plaque volume, calcified plaque volume, and diameter stenosis. In addition, the average per-patient plaque analysis time was 5.7 seconds for the subject device versus 25-30 minutes taken by experts.

3. Comparative Study with the Predicate Device

To establish that the subject device provides clinical performance for total plaque volume, calcified plaque volume, non-calcified plaque volume, and diameter stenosis that is substantially equivalent to the predicate device, a total of 30 lesions (from 27 patients) throughout the coronary artery tree were analyzed using both the subject and predicate devices. The patient population were 60% men and 40% women with a mean of age 64.5 ± 10.1 years. The CT scanner used to collect the images was a commercial Siemens CT scanner. There was an excellent correlation between the subject and predicate devices for total plaque volume, non-calcified volume, calcified plaque volume, and diameter stenosis. These measurements also demonstrated excellent intraclass correlation agreement. It took less than 2 seconds per lesion for the subject device Autoplaque 3.0 to analyze, which was much faster than the predicate device (30 seconds per lesion).

IX. Conclusion

The information provided above supports that Autoplaque 3.0 is as safe and effective as the predicate device. Although there are minor differences between the subject and predicate devices, the differences are addressed through software verification and validation studies, and performance testing. Therefore, it is concluded that Autoplaque 3.0 is substantially equivalent to the predicate device.