September 4, 2025

Careverse Technology Pte. Ltd.
Huiyu Shi
Regulatory Affairs Specialist
987 Serangoon Road
Singapore, 328147
Singapore

Re: K251656
Trade/Device Name: Careverse CoronaryDoc (Careverse CoronaryDoc)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 30, 2025
Received: July 30, 2025

Dear Huiyu Shi:

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,

for

Jessica Lamb, PhD
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.	K251656

Please provide the device trade name(s).

Careverse CoronaryDoc (Careverse CoronaryDoc)

Please provide your Indications for Use below.

Careverse CoronaryDoc is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.
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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K251656

510(k) Summary

1. Submitter

510(k) Submitter

Submitter Name: Careverse Technology Pte. Ltd.

Address: 987 Serangoon Road, Singapore 328147.

Correspondent

Primary Correspondent: Huiyu Shi.

Title: Regulatory Affairs Specialist.

Email: huiyushi@careverse.com

Second Correspondent: Jianfu Wang.

Title: Director of Regulatory Affairs and Quality.

Email: jianfuwang@careverse.com

Date Prepared: 07/29/2025

2. Device

Device Type

Trade Name: Careverse CoronaryDoc (Careverse CoronaryDoc)

Model: Careverse CoronaryDoc.

Common Name: Picture Archiving and Communications System.

Classification

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical image management and processing system

Regulatory Class: Class II

Panel: Radiology

Product Code: QIH

3. Predicate Device

510 (k) number: K202280;
Trade name: Cleerly Labs v2.0;
510(k) submitter/holder: Cleerly, Inc.
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ

4. Device Description

Careverse CoronaryDoc is a B/S architecture and is suitable for DICOM medical image viewing, 3D reconstruction and post-processing and stenosis and plaque analysis. Based on the axial image data of coronary computed tomography angiography (CCTA), Careverse CoronaryDoc automatically extracts the coronary region, detects suspected stenosis lesions in this area, and further performs automatic plaque analysis. At the same time, the software can also automatically detect stents and bridges. Users can modify the degree of stenosis, plaque type, stent, and bridge tips to form a structured report to assist physicians in diagnosing coronary heart disease.

The module functions include user login, image list, vascular segmentation and reconstruction, coronary branch naming, coronary stenosis, plaque, stent, myocardial bridge analysis, plaque detailed analysis, editing segmentation, editing blood vessels, editing naming, image operation tools, structured reports, push printing, management configuration, platform management, and transmission queues.

5. Indications for Use

Careverse CoronaryDoc is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries.

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.

6. Comparison of Technological Characteristic with the Predicate Device

Item	Subject device, K251656	Predicate device (K202280)	Analysis
Product Code	QIH	LLZ	Same
Regulation	21 CFR 892.2050	21 CFR 892.2050	Same
Intended Use/Indications for Use	Careverse CoronaryDoc is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries. 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	Cleerly Labs is a web-based software application that is intended to be used by trained medical professionals as an interactive tool for viewing and analyzing cardiac computed tomography (CT) data for determining the presence and extent of coronary plaques (i.e., atherosclerosis) and stenosis in patients who underwent Coronary Computed Tomography Angiography (CCTA) for evaluation of CAD or suspected CAD. This software post processes CT images obtained using any Computed Tomography (CT) scanner. The software provides tools for the measurement and visualization of coronary arteries. 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	Same

	software's functions, capabilities and limitations.	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.	
Image Input	DICOM 3.0 Compliant	DICOM 3.0 Compliant	Same
Image Acquisition	CT Images	CT Images	Same
Study Analysis Tools – Navigation	Yes	Yes	Same
Study Analysis Tools – Editing/ Visualization	Yes	Yes	Same
2D Imaging	Yes	Yes	Same
3D Imaging	Yes	Yes	Same
Multiplanar Reformat (MPR)	Yes	Yes	Same
Segmentation of Region of Interest	Yes	Yes	Same
Plaque Composition Overlay	Yes	Yes	Same
Hounsfield Unit (HU)	Yes	Yes	Same
Distance Measurements	Yes	Yes	Same

Volumetric Measurements	Yes	Yes	Same
Stenosis	Yes	Yes	Same
Coronary Anatomical Findings	Yes	Yes	Same
Coronary Report	Yes	Yes	Same

7. Performance Data

Software verification and validation activities were performed. During product development, potential hazards were controlled by a risk management plan including activities of risk analysis, risk mitigation, verification and risk-benefit analysis. Verification and validation demonstrated that the device meets all of its specification.

Besides, the performance of the software was compared to ground truth results produced by US expert readers. The results are summarized as the following.

For the segmentation performance, both Dice Coefficient and 95% Hausdorff Distance have met the acceptable criteria. The value of Dice Coefficient is 0.899, which is higher than the acceptable criteria 0.842. The value of 95% Hausdorff Distance is 4.366, which is less than 6.46.

For the labeling performance, the accuracy on case level is 93.10%, the accuracy on vessel level is 98.21%. Results have met the acceptable criteria.

For the stenosis performance, the results are shown in Table 1.

Table 1: Stenosis Performance

Stenosis Grade	n	m	Agreement	Lower 95% CI	Higher 95% CI
non-stenosis	682	675	98.97%	97.90%	99.59%
minor stenosis	160	146	91.25%	85.75%	95.13%
minimal stenosis	100	87	87.00%	78.80%	92.89%
moderate stenosis	94	82	87.23%	78.76%	93.23%
severe stenosis	86	72	83.72%	74.20%	90.80%
complete occlusion	34	31	91.18%	76.32%	98.14%

Notes:

- n: Total number of measurements for that stenosis grade.
- m: Number of measurements where the predicted stenosis grade exactly matched the labeled stenosis grade.

- Agreement: The percentage of measurements in agreement.
- Lower 95% CI: The lower limit of the 95% confidence interval for the agreement percentage.
- Higher 95% CI: The higher limit of the 95% confidence interval for the agreement percentage.

For the plaque performance, the results are shown in Table 2.

Table 2: Plaque Performance

Output	Pearson Correlation Coefficient	Bland-Altman Agreement
vessel volume	98.42%	95.18%
lumen volume	98.52%	94.78%
total plaque volume	96.94%	95.91%
calcified plaque volume	97.92%	98.00%
non-calcified plaque volume	95.14%	95.24%
low-density non-calcified	88.42%	94.96%

8. Standards and Guidance

a) ISO 14971:2019 "Medical devices – Application of risk management to medical devices".
b) ISO/TR 24971:2020 "Medical Device Software GB/T42062 Application Guide".
c) ISO 13485:2016 "Medical devices – Quality management systems – Requirements for use in regulations".
d) IEC 62304:2015
e) GB/T 25000.51-2016 "Systems and software engineering - Quality requirements and evaluation of systems and software (SQuaRE) Part 51: Quality requirements and test rules for ready-to-use software products (RUSP).
f) General Principles of Software Validation; Final Guidance for Industry and FDA Staff, CDRH and FDA, Jan.11, 2012
g) Guiding Principles for Cybersecurity Registration Review of Medical Devices (2022)
h) Guidelines for On-site Inspection of Independent Software in Good Manufacturing Practice for Medical Devices (2020)

9. Conclusion

The proposed device is as safe and effective as the predicate device (K202280). The proposed device has the same intended uses and technological characteristics as its predicate device. Thus, Careverse CoronaryDoc is substantially equivalent.