Caristo Diagnostics
% Mr. James Davis
Head of Quality and Regulatory Affairs
New Barclay House, 234 Botley Road
Oxford, Oxfordshire OX20HP
UNITED KINGDOM

May 21, 2020

Re: K200274
Trade/Device Name: CariCloud v1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 1, 2020
Received: May 4, 2020

Dear Mr. Davis:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200274

Device Name
CariCloud v1.0

Indications for Use *(Describe)*
The indications for use, are as follows:

CariCloud is a software device used by operators to evaluate attenuation in the coronary arteries and surrounding tissue in CCTA images.

CariCloud is to be used by trained operators. CariCloud analysis results are to be used by Healthcare Professionals and may assist in diagnosis.

CariCloud analysis results are indicated for use for all patients referred for CCTA imaging.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## I. SUBMITTER

K200274

Caristo Diagnostics
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Phone: +44 (0) 1865 950720
Contact Person: James Davis
Date Prepared: May 01, 2020

## II. DEVICE

**Name of Device**: CariCloud v1.0

**Common or Usual Name**: CariCloud

**Classification Name**: Picture archiving and communications (21 CFR§ 892.2050)

**Regulatory Class**: II

**Product Code**: LLZ

## III. PREDICATE DEVICE

TeraRecon iNtuition, K121916

This predicate has not been subject to a design-related recall.

## IV. DEVICE DESCRIPTION

CariCloud is an image processing prescription software device intended to be used to display, manipulate and quantify previously acquired CT images.

Datasets are downloaded from remote systems for clinical interpretation. Trained users will initiate and oversee image analysis and intervene when necessary to correct processing errors. The outcome of analysis will be used to create a summary report that includes qualitative and quantitative analysis.

## INDICATIONS FOR USE

The Indications for use are as follows:

- CariCloud is a software device used by operators to evaluate attenuation in the coronary arteries and surrounding tissue in CCTA images.
- CariCloud is to be used by trained operators. CariCloud analysis results are to be used by Healthcare Professionals and may assist in diagnosis.
- CariCloud analysis results are indicated for use for all patients referred for CCTA imaging.

## V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table compares CariCloud v1.0 to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, forming the basis for the determination of substantial equivalence.

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| Manufacturer | Caristo Diagnostics | TeraRecon. INC | Not Applicable |
| 510(k) Number | K200274 | K121916 | Not Applicable |
| Product Code | LLZ | LLZ | Same |
| Regulation Number | 21 CFR 892.2050 | 21 CFR 892.2050 | Same |
| Intended Use / Indications for Use | CariCloud is a software device used by operators to evaluate attenuation in the coronary arteries and surrounding tissue in CCTA images.<br><br>CariCloud is to be used by trained operators. CariCloud analysis results are to be used by Healthcare Professionals and may assist in diagnosis.<br><br>CariCloud analysis results are indicated for use for all patients referred for CCTA imaging. | To receive, store, transmit, post-process, display and allow manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images, DICOM images with modality type XA, US, CR, DR, SPECT, NM and MG, and images from volumetric medical scanning devices such as EBT, CT, PET or MRI.<br><br>To provide access to images derived data and derived images via client-server software, web browser and mobile technology.<br><br>Visualization in 2D, 3D and 4D are supported for single or multiple datasets, or combinations thereof<br><br>Tools are provided to define and edit paths through structures such as centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such a centerline | CariCloud and TeraRecon's iNtuition device can both be used to evaluate attenuation in the coronary arteries and surrounding tissue in CT images.<br><br>CariCloud and TeraRecon's iNtuition device differ in that iNtuition has additional features and supports use in evaluating images from other modalities and diagnostic areas such as oncology and neurology.<br><br>The fact that TeraRecon's iNtuition device supports additional modalities and diagnostic areas does not affect the safety and effectiveness of CariCloud because the additional functionality offered by iNtuition is unrelated to the safety and effectiveness of CCTA image analysis. |

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| | | Segmentation of regions of interest and quantitative analysis tools are provided, for images of vasculature, pathology and morphology, including distance, angle, volume, histogram, ratios thereof, and tracking of quantities over time.<br><br>A database is provided to track and compare results using published comparison techniques such as RECIST and WHO.<br><br>Calcium scoring for quantification of atherosclerotic plaque is supported.<br><br>Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol.<br><br>Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images, such as temporal phases, or images co-located in space but acquired with different imaging parameters, such as different MR pulse sequences, or different CT image parameters (e.g. dual energy).<br><br>INtuition is designed for use by healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions. | |

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| | | Interpretation of mammographic images or digitized film screen images is supported only when the software is used without compression and with an FDA-Approved monitor that offers at least SMpixel resolution and meets other technical specifications reviewed and accepted by the FDA.<br><br>iNtuitionMOBILE provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. Not intended for diagnostic use when used via a web browser or<br>mobile device.<br><br>iNtuition will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete workstation for the end user (software package with harware kit). | |
| Technical Characteristics | | | |
| Data Type | - CT<br><br>- 3D Medical Image Review | - CT, MR, Nuc, PET, Angio, US/Echo, SPECT, CR/DR Review<br><br>- 2D, 3D, 4D Medical Image review including cine play | CariCloud supports CT review. This difference does not affect the safety of the device. |
| Input Patient Data | - Manual through keyboard/mouse<br><br>- Command line interface. | - Manual through keyboard/mouse<br><br>- Command line interface | The same as the predicate device. |
| Study list functionality | - Search | - Importing<br><br>- Exporting<br><br>- Deleting<br><br>- Search<br><br>- Anonymization | CariCloud does not support import, export, delete and anonymization. This difference does not affect the safety of the device. |

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| Centerline Extraction | - Automatic and manual centerlines<br><br>- Centerline edits and refinements.<br><br>- Vessel Analysis<br><br>- Automatic and manual segmentation of structures<br>- Segmentation editing | - Automatic and manual centerlines<br><br>- Centerline edits and refinements.<br><br>- Vessel Analysis<br><br>- Automatic and manual segmentation of structures<br>- Segmentation editing | The same as the predicate device. |
| Image Assessment | - Linear (length, diameter), distance and ROI measurements<br><br>- Area measurements<br><br>- Volume measurements including VOI and thresholding<br><br>- Segmentation and analysis of coronary artery tree centerline<br><br>- Synchronized side-by- side review<br><br>- Synchronized center of rotation viewing | - Linear (length, diameter, perimeter), distance pair, angular and ROI measurements<br><br>- Area measurements<br><br>- Volume measurements including volumetric histogram, VOI and TVA for Time Volume Analysis for heart chamber segmentation and analysis<br><br>- C-arm angulation calculation<br><br>- Text and arrow annotations<br><br>- Anatomy ID (Landmark Label Selection)<br><br>- Calcium scoring for assessment of calcium in the aortic root<br><br>- Calcium scoring for assessment of calcium in the coronary arteries<br><br>- Segmentation and analysis of coronary artery tree centerline<br><br>- Synchronized side-by- side review<br><br>- Synchronized center of rotation viewing | CariCloud supports a sub-set of the image assessment tools that are in the predicate device. This does not affect the safety of the device. |

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| | | - Findings workflow for temporal correlative analysis 2D/3D Batch movie tool and export<br><br>- 2D/3D Batch movie tool and expor | |
| Image Assessment Rendering | - MPR<br><br>- 3D triangulation<br><br>- Curved Planar Reformat (CPR)<br><br>- Synchronized side-by- side viewing<br><br>- Synchronized center of rotation viewing<br><br>- Multi-Mask Display (multi-object display)<br><br>- Editing tools: free- hand | - 2D/3D Batch movie tool and export<br><br>- MIP , MPR, MinIP ,<br><br>- Raysum (ThickMPR)<br><br>- 3D triangulation<br><br>- Perspective endoluminal view<br><br>- Medial Axial Reformat (MAR)<br><br>- Curved Planar Reformat (CPR)<br><br>- Double-oblique MIP and MPR<br><br>- Image enhancement filters<br><br>- Synchronized side-by- side viewing<br><br>- Synchronized center of rotation viewing<br><br>- Cube View | CariCloud supports a sub-set of the image assessment rendering tools that are in the predicate device. This does not affect the safety of the device. |

| Attribute | CariCloud | iNtuition | Comparison |
|---|---|---|---|
| | | - Workflow templates<br><br>- Multi-Mask Display (multi-object display)<br><br>- User-defined measurement protocols<br><br>- Editing tools: crop, cut, free-hand | |
| Storage of results | DICOM SC | - Structured reporting with xml, text, xls output<br><br>- Word and html report<br><br>- DICOM SC<br><br>- Workflow scenes: restore<br><br>saved state | CariCloud supports a sub-set of the result storage tools that are in the predicate device. This does not affect the safety of the device. |
| Conferencing and Collaboration | Not supported. | Conferencing and Collaboration | Not supported. This does not affect the safety of the device. |
| Operating System | Any operating system that supports the Chrome Browser. | Microsoft Windows | CariCloud is supported on the Chrome Browser. This does not affect the safety of the device. |

The agreement in results, inter-operator variability and intra-operator variability attained using both the new device and the predicate device was excellent.

CariCloud v1.0 does not raise any new questions of safety or effectiveness as compared to the predicate device.

# VI. PERFORMANCE DATA

### Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff: "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices." The software level of concern for CariCloud v1.0 is Moderate, as per FDA's guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This device does not control a life supporting or life-sustaining device, does not control the delivery of a potentially harmful energy, does not control the delivery of treatment, does not provide diagnostic information, and does not provide any vital signs monitoring. The hazard analysis identifies the potential software-related risks of using the device, and the mitigations implemented.

### Performance Testing

CariCloud v1.0 software has been developed and tested in accordance with the Caristo Diagnostics Design Control processes and has been subject to extensive safety and performance testing. Non-clinical verification and validation testing has been performed to demonstrate that CariCloud v1.0 meets its design requirements and intended use. Software verification has been conducted at unit and system integration levels. A risk analysis was performed to document the risks associated with the use of the CariCloud v1.0 software product with all identified risks being mitigated. Cybersecurity and data security testing has been conducted to verify that data and patient protected health information security measures are included in the design of the software.

Based on the Verification and Validation testing that has been conducted, CariCloud v1.0 is substantially equivalent to the predicate device.

**Performance Testing - Inter-operator and Intra-operator Variability**
For each device, ICC values were calculated between individual results of each read by each operator on each device for each measure based on an average-rating, absolute-agreement, 2-way mixed-effects model. Theses are shown in the table below.

**Comparison of Intra-Operator Agreement achieved for Each Measure on Each Device:**

| | PFA | | | TVOI-A | | | TVOI-V | | | TROI-A | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **ICC** | **Reader 1** | **Reader 2** | **Reader 3** | **Reader 1** | **Reader 2** | **Reader 3** | **Reader 1** | **Reader 2** | **Reader 3** | **Reader 1** | **Reader 2** | **Reader 3** |
| **Predicate Device** | 0.999 | 0.998 | 0.999 | 0.986 | 0.983 | 0.985 | 0.988 | 0.991 | 0.973 | 1.0 | 1.0 | 1.0 |
| **New Device** | 0.997 | 0.997 | 0.994 | 0.987 | 0.971 | 0.982 | 0.971 | 0.986 | 0.969 | 1.0 | 0.998 | 1.0 |

For all measures, the intra-operator agreement achieved on both the predicate device and the new device for each operator was excellent (ICC greater than 0.96) with a maximum difference in ICC between the two devices was 0.017.
There was no significant difference between the inter-operator variability and intra-operator variability results attained on the two devices.

## VII. CONCLUSIONS

CariCloud v1.0 has the same intended use and the same or similar technological characteristics as the predicate device, TeraRecon iNtuition. The minor differences in the indications do not alter the intended use of CariCloud v1.0 and do not raise any new questions of safety or effectiveness. For this reason, CariCloud v1.0 is substantially equivalent to the predicate device.