AngioCloud, LLC
% Bahram Parvinian
Founder & Principal Consultant
Lighthouse Regulatory Consulting Group, LLC
3 Harrowgate CT
POTOMAC MD 20854

April 28, 2022

Re: K211713
Trade/Device Name: AngioCloud Service
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 14, 2022
Received: March 23, 2022

Dear Bahram Parvinian:

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
Mammography Ultrasound and Imaging Software Branch
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211713

Device Name
AngioCloud Service

Indications for Use *(Describe)*
The AngioCloud Service enables visualization and measurement of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery.

General functionalities are provided such as:
- Segmentation of neurovascular structures
- Centerline calculation
- Visualization of 3D vascular images
- Measurement and annotation tools
- Case sharing and reporting tools

Information provided by the software is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

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.

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510(k) Summary

K211713

Date Prepared
April 25, 2022

Submission Number
K211713

510(k) Submitter
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Device Information

Trade/Proprietary Name	AngioCloud Service
Common Device Name	System, Image processing, Radiological
Classification Name	Medical Image Management and Processing System
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Classification	Class II

Predicate Device
EndoVantage SurgicalPreview™ (K171534)

Reference Device
Visible Patient Suite (K212896)

Device Description
The AngioCloud Service is a standalone web-application which intends to receive a 3D rotational angiography (3D-RA) DICOM dataset and provide interactive views to physicians for the visualization and measurement of cerebral vasculatures during preoperational planning. Physicians can query a 3D-RA dataset directly via the AngioCloud Service provided that they have an internet browser with access to the internet. General functionalities are provided such as:

- Segmentation of neurovascular structures
- Centerline calculation
- Visualization of 3D vascular images
- Measurement and annotation tools
- Case sharing and reporting tools

The AngioCloud Service runs as a web application on a standard Windows or Mac OS X based computer and can also be accessed on mobile web browsers, but with limited software functionalities enabled. The AngioCloud Service does not use any artificial intelligence or machine learning functionality and the main segmentation algorithm is based on level-set methods. The Visualization Toolkit (VTK) and Vascular Model Toolkit (VMTK) serve as important software libraries that the underlying algorithm of AngioCloud Service leverages for a number of computational operations such as 3D segmentation, geometric analysis, mesh generation, and surface data analysis for image-based modeling of blood vessels. The device does not contact the patient nor does it control any life-sustaining devices. Information provided by the AngioCloud Service is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.
The computer hardware used to access the web application must meet the following minimum requirements:

- Operating System: Windows 10 or later, Linux, Android Lollipop and later, iOS 12 or later, Mac OS X 10.10 or later
- Memory: 4 GB RAM
- Hard Disk: At least 200 MB of free hard disk space
- Monitor 1024x768 resolution with 16-bit color
- Web Browser:
    - Google Chrome: since version 83
    - Firefox: since version 77

Indications for Use
The AngioCloud Service enables visualization and measurement of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Centerline calculation
- Visualization of 3D vascular images
- Measurement and annotation tools
- Case sharing and reporting tools

Information provided by the software is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

Comparison of Technological Characteristics with the Predicate Device
The subject device has the same intended use and similar indications for use and technological characteristics (e.g. software for visualization and measurement of cerebral blood vessels for

preoperative planning) to the predicate device (K171534). The differences in technological characteristics between the subject and predicate devices are explained below. AngioCloud does not believe that these differences raise different questions of safety and effectiveness.

- In the predicate device, the input data is a DICOM dataset from all CT scanner vendors, whereas the subject device only accepts volumetric DICOM data acquired by 3D-RA scanners from the Phillips and Siemens X-ray systems. These technological characteristics have undergone testing to ensure the device is substantially equivalent to the predicate.
- In the predicate device, the patient-specific anatomical models that are output by the SurgicalPreview™ software are generated by operators who are in-house EndoVantage employees and allow the end-user clinician to review and comment, whereas the subject device generates anatomical models by the Segmentation Engine. The end-user clinician of the subject device can manually adjust the segmentation threshold or choose an 'Auto' option where an estimated segmentation threshold is adopted for segmentation. These technological characteristics have undergone testing to ensure the device is substantially equivalent to the predicate.
- The predicate device is not indicated for use on a mobile platform whereas the AngioCloud Service is compatible with and can be accessed through a mobile device web browser. Mobile platform access allows for the visualization and sharing of 3D vascular images through the 3D Viewer and for quick ruler and centerline measurements. All other functionalities of the AngioCloud Service are disabled during use on a mobile web browser. This technological characteristic has undergone testing and has been considered as part of the risk assessment to ensure the device is substantially equivalent to the predicate.
- The predicate device is not indicated for case sharing, whereas the AngioCloud Service allows for de-identified cases to be shared between authorized users. Case sharing features have been evaluated through the risk assessment and software verification testing to ensure that this technological characteristic is substantially equivalent to the predicate.

The predicate device has the following additional functionalities which AngioCloud Service does not offer:

- Volume measurements (e.g. aneurysmal volume)
- Line measurements on aneurysm (e.g. aneurysmal neck width and dome height)
- Import patient data via study creation list
- 2D cross-sectional slice review of vessel (e.g. diameter measurement tool)
- Deployment video tool
- Deployment simulation report

AngioCloud believes that the AngioCloud Service's indications for use and technological characteristics are substantially equivalent to the legally marketed predicate device (K171534) based on the information summarized in **Table 1 – Substantial Equivalence Summary**.

Table 1 – Substantial Equivalence Summary

	Subject Device	Primary Predicate Device
Trade Name	**AngioCloud Service**	**SurgicalPreview™**
Manufacturer	**AngioCloud Inc**	**Endovantage**
510(k) Number	**K211713**	**K171534**
Class	II	II
Device Classification Name	System, Image processing, Radiological	Software For Visualization of Vascular Anatomy And Intravascular Devices
Regulation Number	892.2050	892.2050
Product Code	LLZ	PZO
Indications for Use	The AngioCloud Service enables visualization and measurement of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. General functionalities are provided such as: • Segmentation of neurovascular structures • Centerline calculation • Visualization of 3D vascular images • Measurement and annotation tools • Case sharing and reporting tools Information provided by the software is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.	SurgicalPreview™ enables visualization and measurement of vessels for preoperational planning and sizing for neurovascular interventions and surgery. SurgicalPreview™ also allows for the ability to computationally model the placement and deployment of neurointerventional devices. General functionalities are provided such as: • Segmentation of neurovascular structures • Automatic centerline detection • Visualization of CT scan images for 2D review and 3D reconstruction • Measurement and annotation tools • Reporting tools Information provided by the software is not intended in any way to eliminate, replace, or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.
Interface to Image Sources	3D rotational angiography (3D-RA) DICOM image data	CT DICOM image data
Import of Patient Data	Manual through keyboard/mouse, automatic import with image file	Manual through keyboard/mouse, automatic import with image file, study creation list
List Image Functionality	Deleting, anonymizing, search	Same
Image Processing	Segmentation by Segmentation Engine with end-user clinical review and comment.	Segmentation by EndoVantage operator with end-user clinical review and comment.

	Subject Device	Primary Predicate Device
	End-user can manually adjust the segmentation threshold by choosing the 'Advanced' option or apply an estimated segmentation threshold by choosing the 'Automatic' option.	
3D Assessment	Linear (length and diameter) measurements, centerline measurement	Linear (length and diameter) measurements, volume measurements.
Image and 3D Display	Orthogonal, color volume rendering, and 3D visual view of centerline	Orthogonal, color volume rendering, 2D slice review, active presets, 3D view of assemblies of devices
DICOM Support	Compatible with 3D-RA DICOM datasets, storage SCP, import DICOM files, DICOM compliance for 3D-RA CT, storage SCU, query/retrieve SCU	Compatible with all scanner vendor DICOM datasets, storage SCP, import DICOM files, DICOM compliance for CT and enhanced CT, import from DICOMDIR, storage SCU, query/retrieve SCU
Computer OS Compatibility	MS Windows and Mac OS	Same
Mobile OS Compatibility	Yes, mobile browser compatible with limited functionalities	No
Data Interchange / Transfer Method	Secure Internet File Server	Same
Output File Format	Web browser via WebGL	Same
Preoperational Planning	Yes	Same
Patient Contact	No	Same
Human Intervention for Interpretation of Images	Yes	Same

Performance Data

AngioCloud Service is designed in conformance with the following FDA recognized consensus standards:

- NEMA PS 3.1 – 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set
- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
- IEC 62304:2006/AMD 1:2015 – Medical Device Software – Software Life-Cycle Processes
- ISO/IEC 10918-1 First Edition 1994-02-15 Information technology – Digital compression and coding of continuous-tone still images: Requirements and guidelines
- ANSI/AAMI/IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices

All specifications of the AngioCloud Service are verified by a number of tests before release. Non-clinical testing, including verification tests, evaluated:

- DICOM images importation
- Case management
- Auto-segmentation and manual segmentation

- Visualization of 3D vascular images (on desktop and mobile platforms)
- Centerline calculation (on desktop and mobile platforms)
- Measurements and annotation tool (on desktop and mobile platforms)
- Case sharing and reporting tool

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The AngioCloud Service is considered a "moderate" level of concern, since malfunction of the software could cause a delay in generating information for preoperative planning.

Performance testing was conducted to evaluate the AngioCloud Service segmentation module and the device met the pre-defined acceptance criteria for each performance evaluation metric. Anatomically relevant phantom models derived from clinical scans were acquired using Siemens (Artis Q with PURE) and Phillips (Allura Xper FD 20/20) Angio suites. The scans were segmented using AngioCloud Service's 'Automatic' and 'Advanced' segmentation methods and these segmentations were compared to the reference standard. The Hausdorff distance (dH) and DICE coefficient (DC) were used to evaluate segmentation performance. Both the mean DC and mean dH for each group met the acceptance criteria.

AngioCloud believes that the aforementioned non-clinical testing demonstrates that the AngioCloud Service is designed in such a way that, when used in accordance with its indications for use and labeling, the safety and effectiveness, as well as the performance characteristics of the subject device are substantially equivalent to the predicate device.

Substantial Equivalence Conclusion

AngioCloud Service has the same intended use and performance characteristics as the predicate device. Based on the performance data and software verification and validation testing, it can be concluded that the differences in technological characteristics between the AngioCloud Service and the predicate device do not raise different questions of safety and effectiveness. The indications for use, technological characteristics, and performance characteristics for the AngioCloud Service are assessed to be substantially equivalent to those of the predicate device.