March 16, 2020

Integrated Ophthalmic Systems, Inc.
% Anna Reifschneider
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 444
Ludlum, Florida 33155-3708

Re: K200385
Trade/Device Name: Continuum PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: February 17, 2020
Received: February 18, 2020

Dear Ms. Reifschneider:

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,

Elvin Ng
Acting Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K200385

Device Name
CONTINUUM PACS

Indications for Use *(Describe)*
CONTINUUM PACS is a software system to store, manage and display patient data, diagnostic data, videos and images from computerized ophthalmic diagnostic imaging devices

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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510(k) Summary

Submitted By

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Date Prepared

December 23, 2019

Submission Type

Traditional 510(k)

Trade Name

CONTINUUM PACS

Common Name

Ophthalmic Image Management System

Classification Name

System, Image Management, Ophthalmic
CFR Number: 21 CFR 892.2050
Product Code: NFJ
Class II

Indications for Use

CONTINUUM PACS is a software system to store, manage and display patient data, diagnostic data, videos and images from computerized ophthalmic diagnostic imaging devices.

Predicate Device

Sonomed, Inc.
AXIS Image Management System
K171098
CFR Number: 21 CFR 892.2050
Product Code: NFJ

Description of the Device

CONTINUUM PACS is an ophthalmic image management system that has been designed to store, retrieve and provide browser-based review of reports, videos and images which were generated by ophthalmic imaging devices.

CONTINUUM PACS and the predicate device both are software systems designed to operate on the user's network, which may consist of a server, computers and network infrastructure.

CONTINUUM PACS has a central database for patient information and historical exams. CONTINNUM PACS is installed on the user's server and communicate with the networked imaging devices. The users review images, reports, and videos via their existing browser software.

Images can be obtained from diagnostic devices using numerous industry standards, including DICOM, JPEG, PDF, WMV, AVI.

Comparison to Predicate Device

CONTINNUM PACS and the AXIS Image Management System predicate device are the same in terms of intended use, performance and technological characteristics and is therefore substantially equivalent to the Axis Image Management System. The intended use of both devices is the same in that they are both intended to store, manage and display patient data from ophthalmic diagnostic imaging devices.

Both systems have a central database for storing patient data and store diagnostic images, such as retinal images and images from other ophthalmic diagnostic devices that are transferred by network connection.

CONTINUUM PACS and the predicate device are both software systems that function on the user's network infrastructure, which may include a server, computers and network infrastructure.

CONTINUUM PACS and the predicate device provide the ability for the user to search the database for patients and their respective images and to display multiple images for comparison. Both devices can be used to access the data from remote locations with web access. CONTINUUM PACS and the predicate device serve the same clinical purpose and provide the same functionality.

The following table provides a comparison of the technological characteristics to the predicate device:

Characteristic	CONTINUUM PACS	AXIS Image Management
Software-only system	Yes	Yes
Patient database	Yes	Yes
Imaging review capability	Yes	Yes
Image annotation and measurement capability	Yes	Yes
Browser-based application	Yes	Yes
User interface design	HTML5	Silverlight
Secure login	Yes	Yes
Interface with electronic medical records (EMR)	Yes	Yes
Connects to imaging instruments vis DICOM and non-DICOM methods	Yes	Yes

The only minor difference in technology between the 2 products is the user interface design in the AXIS Image Management System was developed in Silverlight, and in the CONTINUUM PACS the user interface was developed in HTML5.

Evaluation performed on CONTINUUM supports the indications for use statement, demonstrates that the device is substantially equivalent to the predicate device, and does not raise any new questions regarding safety and effectiveness.

Non-Clinical Performance Data

Performance testing was performed on CONTINUUM PACS during software verification and validation and was found to perform as intended. CONTINUUM PACS is DICOM compliant, as specified in its DICOM Conformance Statement. There is no stated shelf-life, as CONTINUUM PACS is a software-only device.

Conclusions from Non-Clinical Data

Based upon the results of the data as summarized above, CONTINUUM PACS has demonstrated that it is as safe, effective and performs as well as or better than the predicate device. Furthermore, based on the comparison with the predicate device as shown in the summary above, CONTINUUM PACS is deemed to be substantially equivalent to the predicate device.

Clinical Performance Data

None required or submitted.