DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 2, 2017

Sonomed, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K171098
Trade/Device Name: AXIS Image Management System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: April 11, 2017
Received: April 13, 2017

Dear Mr. Mark Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171098

Device Name

AXIS Image Management System

Indications for Use *(Describe)*

Storage, management, and display of 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.

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Sonomed, Inc.
510(k) Application: AXIS Image Management System

Section 1: 510(k) Summary

Submitted By

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2433682

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Date Prepared

August 9, 2016

Submission Type

Traditional 510(k)

Trade Name

AXIS Image Management System

Common Name

System, Image Management, Ophthalmic

Classification Name

Picture Archiving and Communications Systems

CFR Number: 892.2050
Product Code: NFJ

Intended Use

Storage, management, and display of patient data, diagnostic data, videos, and images from computerized ophthalmic diagnostic imaging devices.

Legally-Marketed Equivalent Devices

Carl Zeiss Surgical GmbH
FORUM
(k090439)

Description of the Device

AXIS Image Management System is a browser-based ophthalmic image management system designed for storage, retrieval, and review of images, videos, and reports originating from ophthalmic imaging devices.

AXIS Image Management System and the predicate device are software systems that work on standard network infrastructure provided by the user. Such infrastructure may include a server, network, and computing devices.

AXIS Image Management System provides a central database of patient information and exam image history. The AXIS software resides on a server provided by the user and interfaces with networked imaging instruments. Users utilize their existing browser to access the AXIS software to review images, videos, and reports.

Images can be obtained from diagnostic devices in a variety of industry-standard formats including PDF, JPEG, DCM, and AVI.

Comparison to Predicate Device

It is the opinion of Sonomed, Inc. that AXIS Image Management System is substantially equivalent to the predicate device, FORUM from Carl Zeiss Surgical GmbH (k090439), as they share similar fundamental technological characteristics. Both systems are comprised of a central database to store diagnostic documents (such as retinal images and images from other ophthalmic diagnostic devices). These documents are imported from the diagnostic devices via a networked connection.

Both AXIS Image Management System and the predicate device are software systems that work on standard network infrastructure provided by the user. Such infrastructure may include a server, network, and computing devices.

Both AXIS Image Management System and the predicate device allow a user to search the database for patients and their respective documents and to display multiple documents for comparison

purposes. In both cases, the software can be used to access the database from a remote location via web-based access.

AXIS Image Management System and the predicate device serve the same principal purpose of clinical usage and provide a wide range of comparable functionality; the table below provides a comparison of technological characteristics with the predicate device.

Characteristic	AXIS	FORUM (k090439)
Software-only system	Yes	Yes
Patient database	Yes	Yes
Imaging review capability	Yes	Yes
Image annotation and measurement capability	Yes	Yes
Application	Browser on reviewing device accesses server (no special software installed on reviewing device)	Client software installed on reviewing device, which accesses server
Secure Login	Yes	Yes
Interface with electronic medical records (EMR)	Yes	Yes
Connects to imaging instruments via DICOM and non-DICOM methods	Yes	Yes

The only characteristic difference shown is the manner in which the applications are provided to users. In the case of FORUM, a client application software is installed onto each reviewing device, which then connects to the database software residing on the server. In the case of AXIS Imaging Management System, the database software residing on the server is accessed through an Internet browser program on the reviewing device. The particular program used is the choice of the user (e.g. Microsoft Internet Explorer, Apple Safari, etc.). In this manner, the use of AXIS Image Management System is review device agnostic, and is simpler for the user facility to maintain and use.

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

Non-Clinical Performance Data

Performance testing was conducted on AXIS Image Management System as part of the software verification and validation and was found to perform as intended. AXIS is DICOM-compliant as stipulated in its DICOM Conformity Statement. There is no stated shelf-life since AXIS is a software device only.

Clinical Performance Data

None required or submitted.

Conclusions from Non-Clinical (and Clinical) Data

Based upon the results of the data as summarized above, AXIS Image Management System has demonstrated that it is as safe, as 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 discussion above, as well as guidance provided by FDA 510(k) Substantial Equivalence Decision-Making Process Flowchart, AXIS Image Management System is deemed to be substantially equivalent to the predicate device.