



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Anatomage Inc.
% Mr. Sean Xu
Program Director
111 N. Market Street, #500
SAN JOSE CA 95113

June 4, 2015

Re: K150976
Trade/Device Name: Collage
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 14, 2015
Received: April 15, 2015

Dear Mr. Xu:

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 yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. A faint, semi-transparent "FDA" watermark is visible behind the signature.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150976

Device Name

Collage

Indications for Use (Describe)

Collage is a software application intended for viewing of 3D medical image files from scanning devices, such as CT, MRI, or 3D Ultrasound as well as 2D patient images, such as patient photographs, intraoral photographs, and dental x-rays. Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. It is intended for use by doctors, clinicians, and other qualified individuals utilizing standard PC hardware.

This device is not indicated for mammography use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510K Summary

Submitter	Anatmage Inc. 111 N. Market Street #500 San Jose, CA 95113 Phone: (408) 885-1474 Fax: (408) 295-9786
Regulatory Contact Person	Sean Xu, Program Director Phone Number: (408) 885-1474 ext 108
Device Name	Collage
510(k) Preparation Date	04/08/2015
Common Name	System, Image Processing, Radiological
Classification	Class II
Classification Name	Imaging Processing System, LLZ, 21 CFR 892.2050
Product Code	LLZ, 21 CFR 892.2050
Device Description	<p>Collage is an interactive imaging software used for the visualization, storage, and management of 3D medical image files from scanning devices, such as CT, MRI, or 3D Ultrasound as well as 2D patient images, such as patient photographs, intraoral photographs, and dental x-rays. Doctors, dental clinicians, and other qualified individuals can retrieve, process, render, review, store and print images, utilizing standard PC hardware. The software runs in Windows operating systems and visualizes medical imaging data on the computer screen. The Collage software is intended as a platform bridging different sets of patient data for comprehensive studies. With Collage software, doctors can manage all of their patient images, including both 2D and 3D image data, in a single software.</p>
Intended Use	<p>Collage is a software application intended for viewing of 3D medical image files from scanning devices, such as CT, MRI, or 3D Ultrasound as well as 2D patient images, such as patient photographs, intraoral photographs, and dental x-rays. Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. It is intended for use by doctors, clinicians, and other</p>

qualified individuals utilizing standard PC hardware.

This device is not indicated for mammography use.

Equivalent Devices

K101342, OsiriX MD

Technological Characteristic

Collage is a software that handles digital medical images. This device does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by this software but by doctors, clinicians and other qualified individuals. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.

Collage is installed on standard off-the-shelf x86 processor based computers running the Windows operating system.

Non-Clinical Test Results

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing
- Usability testing
- Final acceptance testing
- Bench testing to compare with predicate software

Testing confirmed that the software is stable and operating as designed. Testing also confirmed that the software has been evaluated for hazards and that risk has been reduced to acceptable levels.

Bench testing of the software with predicate software was performed by evaluation of images rendered by Collage and predicate software. This testing and evaluation included testing of rendering both 2D and 3D images in both predicate and subject software and was evaluated by an expert in the field of radiology. This testing confirms that Collage is as effective as its predicate in its ability to perform its essential functions of rendering and managing medical images.

Summary

Based on the intended use, product, performance, and testing information provided in this notification, the subject device has been shown to be substantially equivalent in the area of technical characteristics, general functionality, and indicated use to the currently marketed predicate device and does not introduce any new potential risks.