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

January 4, 2017

Anatomage, Inc.
% Mr. Changxin Xu
Program Director
303 Almaden Blvd., #700
SAN JOSE CA 95110

Re: K161270
Trade/Device Name: CephSimulation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 23, 2016
Received: November 29, 2016

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K161270

Device Name
CephSimulation

Indications for Use *(Describe)*
CephSimulation is a software application intended for storing and visualization of patient images and assisting in case diagnosis and surgical treatment planning. Results of the software are to be interpreted by trained and licensed dental and medical practitioners. It is intended for use by dentist, medical surgeons, and other qualified individuals using a standard PC.
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.

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510K Summary

I. Submitter

Anatomage Inc.
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Contact Person: Changxin Xu, Program Director
Preparation Date: 4/29/2016

II. Device

Device Name	CephSimulation
Common Name	Radiological Image processing System
Classification	Class II
Classification Name	Radiological Imaging Processing System, 21 CFR 892.2050
Product Code	LLZ

III. Predicate Device

Primary Predicate Device: K110430, Dolphin Imaging

Reference Device: K123519, InVivoDental

IV. Device Description

CephSimulation is an interactive imaging software device. It is used for the visualization of patient image files from scanning devices such as CT scanners, and for assisting in case diagnosis and review, treatment planning and simulation for orthodontic and craniofacial applications. Doctors, dental clinicians, medical surgeons and other qualified individuals can render, review and process the images, perform measurement, analysis and surgery simulation. The software runs with standard PC hardware and visualizes imaging data on standard computer screen.
CephSimulation is designed as a plug-in component for InVivoDental software. It is seamlessly integrated into InVivoDental for extended capabilities. The key functionality includes image visualization, cephalometric tracing and measurements and 3D surgery simulation.

V. Indication for Use

CephSimulation is a software application intended for storing and visualization of patient images and assisting in case diagnosis and surgical treatment planning. Results of the software are to be interpreted by trained and licensed dental and medical practitioners. It is intended for use by dentist, medical surgeons, and other qualified individuals using a standard PC. This device is not indicated for mammography use.

The indication for Use statement for CephSimulation is not identical to the primary predicate

device. However, the difference is CephSimulation is not indicated for mammography use. This restriction does not affect the safety and effectiveness of the device relative to the predicate.

VI. Technical Characteristics and comparison with the predicate device

CephSimulation is a software only device 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, surgeons and other qualified individuals. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed and printed.
CephSimulation is installed on standard off-the-shelf x86 processor based computers.

Comparison of the proposed devices with the primary predicate device and reference device is summarized in the following table:

Characteristic	Proposed Device (CephSimulation)	Primary Predicate Device (Dolphin Imaging)	Reference Device (InVivoDental)
501(k) number	Pending	K110430	K123519
Indication for use	CephSimulation is a software application intended for storing and visualization of patient images and assisting in case diagnosis and surgical treatment planning. Results of the software are to be interpreted by trained and licensed dental and medical practitioners. It is intended for use by dentist, medical surgeons, and other qualified individuals using a standard PC. This device is not indicated for mammography use.	Dolphin Imaging software is designed for use by specialized dental practices for capturing, storing and presenting patient images and assisting in treatment planning and case diagnosis. Results produced by the software's diagnostic and treatment planning tools are dependent on the interpretation of trained and licensed practitioners.	InVivoDental is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRJ, or 3D Ultrasound. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, store, print, assist in diagnosis, and dis tribute images utilizing standard PC hardware. Additionally, InVivoDental is a preoperative software application used for the simulation and evaluation of dental implants, orthodontic planning and surgical treatments. This device is not indicated for mammography use.
Operation system	Windows	Windows or Mac OS	Windows

User interface	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard
Technology Platform	PC based	PC and MAC	PC based
Standalone software	Plug-in view of InVivoDental (K123519)	Yes	Yes
Image rendering	2D and 3D	2D and 3D	2D and 3D
Image manipulation	Preview, Rotate, Enhance, Zoom, Brightness, Contrast	Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness	Preview, Rotate, Enhance, Zoom, Brightness, Contrast, Sharpness
Basic Image measurement	Distance, angle	Distance, angle	Distance, angle
Cephalometric measurement	Distance, angle, ratio, difference	Distance, angle, ratio, difference	None
Cephalometric tracing	Manual point picking and structure drawing, Software provides predefined landmarks, structures and allows user to define their own. Can trace on 3D volume.	Manual point picking and automatic structure templates Software provides predefined landmarks and tracing structures. Can trace on 3D volume and 2D photo.	None
Cephalometric analysis	Provides both 3D and 2D analysis. All measurements are created in 3D. 2D analysis is created by projecting 3D measurements onto plane (mid-sagittal plane). Standard orthodontic tracing analyses and user-configurable analysis: Lateral Analyses: - ABO - Alabama - Steiner - Alexander - Downs	Provide both 3D and 2D analysis. 3D analysis is performed on 3D volume. 2D analysis is performed on 2D photo or x-ray. Standard orthodontic tracing analyses and user-configurable analysis: Lateral Analyses: - Ricketts - McNamara - Steiner (Tweed) - Jarabak - Roth - Sassouni - McLaughlin - Downs-Northwestern - Bjork - Alexander (Vari-	None

	- Iowa - McLaughlin - McNamara - Summary - Tweed - Univ. of Pacific - Ricketts - Bjork - Sassouni BottomLine Frontal Analyses: - Grummons Simplified Frontal - Grummons Simplified Midline - Grummons Plus Frontal - Grummons Plus Height, Angle, Ratio 3D Analyses: - Cranial Skeletal - Cranial Dental	Simplex) - Holdaway - Alabama - Burstone - … more than 400 in all Frontal Analyses: - Ricketts - Van Arsdale - Grummons - Grummons Simplified Arch Analysis (Models Study) - Bolton - Schwarz	
Tracing superimposition	Yes	Yes	No
Wigglegram	Yes. Allow user to enter norms and standard deviations.	Yes. Allow user to enter norms and standard deviations.	No
Profilogram	Yes	No	No
Occlusal gram	Yes	No	No
2D growth simulation	No	Yes. Growth forecast on traced x-ray or tracing overlaid on photo	No
Treatment planning and simulation	Orthodontic and craniofacial applications using predefined maxillary, mandible, chin, and cheek cuts. User can translate, rotate the cuts.	Orthodontic and orthognatic applications using maxillary, mandible, and chin cuts. User can translate, rotate the cuts.	No surgery cut functions.
Soft tissue deformation	Yes. 3D only.	Yes. 2D and 3D	No
Photo wrapping	Can wrap 2D and 3D	Can wrap 2D and 3D	None

	photos on volume image	photos on volume image	
Implant module	Not in this device	Yes (IMPLANNER)	Yes
Scanner connection	No	Yes	No
DICOM support	Yes (through host device: InVivoDental K123519)	Yes	Yes

VII. Performance Data

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

· Risk Analysis
· Traceability Analysis
· 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 major function outputs from CephSimulation and predicate software. The testing result was evaluated by an expert in the field of radiology. This testing confirms that CephSimulation is as effective as its predicate in its ability to perform essential functions.

VIII. Conclusions

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.