September 21, 2018

Anatomage Inc.
Changxin Xu
Regulatory Manager
303 Almaden Blvd. Suite 700
SAN JOSE, CA 95110

Re: K181926
Trade/Device Name: InVivo Web Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 13, 2018
Received: July 18, 2018

Dear Changxin 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181926

Device Name
InVivo Web Viewer

Indications for Use *(Describe)*
InVivo Web Viewer is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT and MRI. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to retrieve, process, render, review, assist in diagnosis, utilizing web user interface. Additionally, InVivo Web Viewer is a preoperative software application used for the planning and evaluation of dental implants and surgical treatments.
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.

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"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 Information:**

  Anatomage Inc.
  303 Almaden Blvd., Suite 700
  San Jose, CA 95110
  Phone: (408) 885-1474
  Fax: (408) 295-9786

  Preparation Date: 7/13/2018

- **Contact Person**

  Changxin Xu, Regulatory Manager
  Phone Number: (408) 885-1474 ext 108

- **Device**

Trade Name:	InVivo Web Viewer
Regulation Name:	Picture archiving and communications system
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
510(k) Number	K181926

- **Predicate Device**

Trade Name:	InVivoDental
Regulation Name:	Picture archiving and communications system
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
510(k) Number	K123519

- **Device Description**

  InVivo Web Viewer is an imaging software designed specifically for clinicians, doctors, physicians and other qualified medical professionals. It is used for the visualization of patient image files from scanning devices, such as CT and MRI, and for assisting in case diagnosis, dental implant placement and treatment planning.
  It displays 2D image and renders 3D volumetric image in web browser environment such as Google Chrome or Mozilla Firefox. Users are able to examine anatomy on a computer screen and manipulate the rendered image by turning, zooming, clipping, adjusting brightness and contrast and choosing different rendering color presets. User can also make distance measurements on the image and use the implant placement tool for assisting implant placement and surgical treatment planning.

- **Intended Use**

  InVivo Web Viewer is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT and MRI. It is intended for use by radiologists, clinicians, referring physicians and other qualified individuals to

retrieve, process, render, review, assist in diagnosis, utilizing web user interface. Additionally, InVivo Web Viewer is a preoperative software application used for the planning and evaluation of dental implants and surgical treatments.
This device is not indicated for mammography use.

- **Technological Characteristic**

  InVivo Web Viewer is a software only device that handles digital medical images on dedicated workstations. This devices does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by this software but by doctors, physicians and other qualified medical professionals. A physician, providing ample opportunity for competent human intervention, interprets images and information being displayed.
  InVivo Web Viewer provides distance measurement tool for facilitating its intended use. The measurement accuracy is the image resolution it reads.

  InVivo Web Viewer and InVivoDental are compared below.

Item	**This Device (InVivo Web Viewer)**	**Predicate Device (InVivoDental K123519)**
Principle of operation	Web application running in web browser.	Desktop software application.
Programming language	Javascript, html, css	C++
Functions		
Image rendering	2D gray scale rendering and 3D volumetric rendering	2D gray scale rendering and 3D volumetric rendering
Image manipulation	Brightness/contrast adjustment for both 2D and 3D image Rotate, zoom, pan for 3D image Zoom and pan for 2D image Change color presets for 3D image	Brightness/contrast adjustment for both 2D and 3D image Rotate, zoom, pan for 3D image Zoom and pan for 2D image Change color presets for 3D image
Mesh rendering	Yes	Yes
Measurement	Distance	Distance, angle, area and volume
User interface	One tab window	Multiple tab windows
Implant placement	Implant placement, move, rotate, delete and parameter change	Implant placement, move, rotate, delete and parameter change
Image superimposition	No	Yes
Annotation	No	Yes
Cross section	Yes	Yes
Nerve visualization	Can visualize nerve but cannot create	Can create and visualize

DICOM 3.0 Conformance	Yes	Yes

Analysis of similarities and differences:
The proposed device has similar indication for use and similar basic functions comparing to the predicate device. Both provided the basic functions such as 2D and 3D image visualization and manipulation and implant placement and editing. However, due to the differences in the principle of operation, InVivo Web Viewer has simplified user interface and less tools for user to process the image because it runs in the web browser. The differences does not raise any new potential safety issues.

- **Non-Clinical Test Results**

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

  - Risk Analysis
  - Traceability Analysis
  - Design Reviews
  - Unit testing
  - Performance testing
  - Usability testing
  - Final acceptance testing

  The documented testing results 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 and lowest possible levels.

  Bench testing of the software with predicate software was performed by evaluation of major function outputs from InVivo Web Viewer and predicate software. This testing confirms that InVivo Web Viewer is as effective as its predicate in its ability to perform essential functions.

- **Summary**

  Based on the intended use, technological characteristics, performance, and testing information provided in this notification, the subject device has been shown to be substantially equivalent in the areas of technical characteristics, general functionality, and indication for use to the currently marketed predicate device and does not raise any new issues of safety or effectiveness.