K123519

FEB 0 1 2013

5. 510K Summary

Submitter	Anatomage Inc. 111 N. Market Street #800 San Jose, CA 95113 Phone: (408) 885-7471 Fax: (408) 295-9786
Contact Person	Mike Mendez Phone Number: (408) 885-7471 ext 119
Device Name	InVivoDental
510(k) Preparation Date	11/02/12
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	InVivoDental is a volumetric imaging software designed specifically for clinicians, doctors, physicians, and other qualified medical professionals. The software runs in Windows operating systems and visualizes medical imaging data on the computer screen. The software is downloaded over the internet and installed on the customer's computer. Users are able to examine anatomy on a computer screen and use software tools to move and manipulate rendered images by turning, zooming, flipping, adjusting contrast and brightness, cutting, and slicing. There are several rendering settings to emphasize bone and/or soft tissue. The software also has the ability to create panoramic images, superimpose images, and create measurements of volume, angle, and length. There are multiple tools to annotate and otherwise mark areas of interest on the images. The software has specialized tools to simulate surgical treatments using models rendered by Antomage, and any view or user modified area can be saved to a gallery. These simulations and galleries can then be reviewed by medical personnel or used for consultation between the doctor and

patient.

Intended Use

InVivoDental is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, 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 distribute 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.

Equivalent Devices

K070803	Anatomage, InVivoDental
K081347	IMTEC ILUMA Vision v2.0

Technological Characteristic

InVivoDental and the predicate devices are standalone software. All of these software devices are designed to be installed on standard off-the-shelf x86 processor based computers running the Windows operating system. DICOM data from medical imaging devices are visualized as volume or 2D images.

A difference between InVivoDental and the predicate software is the output of DICOM files. DICOM files can be distributed and read by a device that reads DICOM files while the format that InVivoDental exports is intended to be read by the InVivoDental reader. This does not impact safety or effectiveness of the device. Limiting the rendering of images to Anatomage software allows for consistent rendering of images and information by eliminating the use of substandard software that is freely distributed on the internet.

Non-Clinical Test Results

Testing confirmed that the software is stable and operating as designed.

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Final acceptance testing (Validation)
- Bench testing to compare with predicate software

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

Bench testing of the software with predicate software was performed by evaluation of images rendered by InVivoDental and predicate software. This testing and evaluation included testing of measurement tools in both predicate and subject software and was performed by an expert in the field of radiology. This testing confirms that InVivoDental is as effective as its predicates in its ability to perform its essential functions of measurement and rendering of DICOM data.

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 technology, functionality, and indicated use to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 1, 2013

Anatomage, Inc.
c/o Mr. Mike Mendez
Official Correspondent
111 N. Market Street, Suite 800
SAN JOSE CA 95113

Re: K123519
Trade/Device Name: InVivoDental
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2012
Received: November 15, 2012

Dear Mr. Mendez:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications For Use Statement

510(k) Number (if known): _____

Device Name: InVivoDental

Indications for Use:

InVivoDental is a software application used for the display and 3D visualization of medical image files from scanning devices, such as CT, MRI, 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 distribute 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.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)
Evaluation and Safety
510(k) K123519

Page 1 of ___