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

Imaging Sciences International / Gendex / Dexis
% Sanjay Ahuja, Ph.D.
Director of Regulatory Affairs
1910 North Penn Road
HATFIELD PA 19440

October 7, 2015

Re: K151941
Trade/Device Name: Dexis Webview
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 28, 2015
Received: September 18, 2015

Dear Dr. Ahuja:

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,

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)*
K151941

Device Name
Dexis Webview

Indications for Use *(Describe)*
Dexis Webview is a web-based software used for general dental and maxillofacial diagnostic image review that allows users alternate access to image data using a common web-browser. It provides the ability to view, enhance, annotate, compare, and export images by accessing an existing image database available in a distributed environment.

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
PRAStaff@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."

510(K) Summary

Dexis Webview

Submitter's Name, Address, Telephone Number
Dental Imaging Technologies Corporation (dba Imaging Sciences International LLC, dba Gendex LLC, Dexis LLC)
1910 North Penn Rd.
Hatfield, PA 19440

Contact Person
Sanjay Ahuja, Ph.D.
Email: sanjay.ahuja@kavokerrgroup.com
Telephone: (267) 954-1463
Fax: (215) 997-5665.

Date Prepared
13 July 2015

Name of Device
Dexis Webview

Name/Address of Sponsor
Dental Imaging Technologies Corporation (dba Imaging Sciences International LLC, dba Gendex LLC, Dexis LLC)
1910 North Penn Rd.
Hatfield, PA 19440

Common or Usual Name
Dental Imaging Device

Product Code
LLZ

Classification Name
System, Image Processing, Radiology, per 21 CFR §892.2050.

Predicate Devices
Dexis Software (K140445)

Intended Use / Indications for Use

Dexis Webview is a web-based software used for general dental and maxillofacial diagnostic image review that allows users alternate access to image data using a common web-browser. It provides the ability to view, enhance, annotate, compare, and export images by accessing an existing image database available in a distributed environment.

Dexis Webview is indicated for use only by prescription and by a trained and qualified dentist or dental technician.

Device Description

Dexis Webview is a web browser-based accessory software application that allows users to access pre-existing imaging data remotely. Users are able to view, enhance, annotate, compare, and export pre-existing images using the Dexis Core database using a web-browser. The intended use of the device is to allow dentists to be able to diagnose remotely using a traditional web-browser running on a desktop PC or Apple Mac.

Technological Characteristics

The following are the technological characteristics between the Dexis Webview (K151941) and the cleared version of the Dexis Software (K140445):

Attribute	**DEXIS Software (K140445)**	**Proposed Dexis Webview (K151941)**
Type	Software only	Software only
Host Platform	PC & Apple Mac	PC & Apple Mac
Operating System	Microsoft Windows® XP Pro (32bit), Microsoft Windows® Vista (32bit), Microsoft Windows® 7 Pro (32bit or 64bit). Note: Most supported devices do not have 64bit drivers and thus need the 32bit version of Microsoft Windows 7 Apple Mac OS, minimum version 10.8	All compatible Web-browsers running under the following Operating Systems: Microsoft Windows® XP Pro (32bit), Microsoft Windows® Vista (32bit), Microsoft Windows® 7 Pro (32bit or 64bit). Note: Most supported devices do not have 64bit drivers and thus need the 32bit version of Microsoft Windows 7 Apple Mac OS, minimum version 10.8
Host RAM	Windows: Workstations: 1GB or higher; Servers: 1GB or higher Mac: Workstations: 4GB or higher; Servers: 4GB or higher	n/a
Host magnetic storage	Windows: Workstations: 80GB or larger; Servers: 120 GB or larger Mac: Varies for different Apple Mac OS devices, 1GB minimum of available disk space for installation	n/a
CD ROM	No. DVD or USB or Network Download (for Installation)	No. DVD or USB or Network Download (for Installation)
Host Processor Speed	Windows: Intel® Pentium® 4 or higher Mac: None specified	Windows: Intel® Pentium® 4 or higher Mac: None specified
Host Monitor Size	Windows: SVGA, XGA recommended Mac: None specified.	Windows: SVGA, XGA recommended Mac: None specified.
Display resolution	Windows: 800 x 600 with a minimum of .25 dot pitch Mac: 1280 x 768 pixels minimum	Windows: 800 x 600 with a minimum of .25 dot pitch Mac: 1280 x 768 pixels minimum

Attribute	DEXIS Software (K140445)	Proposed Dexis Webview (K151941)
Receive Images from other systems	Yes	Yes
Images Displayed	Dental X-rays, intraoral and extraoral Images	Dental X-rays, intraoral and extraoral Images
Programming Code	Windows: 32-bit and 64-bit code Mac: 64-bit code.	Windows: 32-bit and 64-bit code Mac: 64-bit code.

The Dexis Webview software uses common web browsers (Internet Explorer, Chrome, etc) with regards to viewing, enhancing, annotating, comparing, and exporting images using the Dexis Core database in an alternate fashion similar to the access provided by the Dexis software and aiding in the practitioner's decision making process. The following is the functionality comparison:

Functionality	Dexis (K140445)	Proposed Dexis Webview (K151941)
Overall Functionality	The main imaging program for X-rays and color images.	A remote viewer application for X-rays and color images.
Overall Functionality	Includes functions to acquire images from various sources, enhancement, annotation, measurement, import/export and printing. Provides image acquisition workflows, dental image display, and radiograph enhancements.	Includes functions to analyze acquired images from various sources, enhancement, annotation, measurement, import/export and printing. While it does not provide image acquisition workflows, it does provide dental image display, and radiograph enhancements.
Database	Images and metadata are stored in the Dexis database.	Images and metadata are stored in the Dexis Core database.
Driver Support	Acquires and displays dental images from other imaging sensors.	Analyzes and displays dental images from other imaging sensors which are stored in the Dexis core database.
Accessibility	Can be accessed over a distributed network	Can be accessed over a distributed network

The Dexis Webview Software is a software program for general dental and maxillofacial diagnostic imaging. It provides the ability to view, enhance, annotate, compare, and export images by accessing an existing image database available in a distributed environment. It allows remote access to x-ray digital images acquired from digital imaging systems. It can also handle other types of images acquired by digitizing film with a flatbed scanner, or color images from intraoral or extraoral dental cameras as long as they are stored in an accessible database.

Dexis Webview allows the following functionality remotely using a standard web-browser:

- Access and analyze x-ray images acquired from imaging plates with the Photo-Stimulable Phosphor (PSP) scanners.
- Access and analyze x-ray images acquired using from intra-oral and extra-oral sensors.
- Access patient files remotely via a standard web-browser with established network connectivity.
- Access and view color images from intra-oral and extra-oral cameras,
- Access, export, and import digital images (such as those obtained by scanning a film) in several standard file formats.
- Process images with dental specific tools, to enhance their diagnostic value.
- Analyze and enhance images in order to gather additional diagnostic information which may not be immediately apparent on initial visual inspection.
- Print images and image-related information over the network.

Dexis Webview is typically utilized remotely using a web-browser over a networked environment.

Substantial Equivalence

The Dexis Webview web-browser Software with the updated Indications for Use and intended use described in this submission is substantially equivalent to the Dexis Software cleared under K140445. It also satisfies all criteria of substantial equivalence based upon the above comparisons in the sections and does not raise new concerns in safety and effectiveness: (1) Indications for Use, (2) Technological Characteristics, and (3) Theory of Operations. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is safe and effective. Thus, the Dexis Webview (proposed under K151941) is substantially equivalent to the cleared Dexis Software (K140445).

Performance Data

Whereas Dexis Software can capture digital images from various sensors (e.g. intraoral), Dexis Webview can only view, enhance, annotate, compare, and export already acquired images by remotely accessing such images over the network. The proposed device has the same fundamental scientific technology, has not been reclassified, and has an intended use which correlates with that of the predicate device. The safety and effectiveness of the Dexis Webview web-browser software was evaluated via bench testing, verification and validation testing, and conformance to international conformance standards. The Dexis Webview Software performs equivalently in functionality as the cleared Dexis Software (K140445) with regards to viewing, enhancing, annotating, comparing, and exporting images by remotely accessing an existing image database available in a distributed environment. Dexis Webview complies with the following relevant standard: ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. Performance data (Verification and Validation) demonstrate that Dexis Webview web-browser software functions equivalently to the Dexis Software predicate device.