DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 25, 2017

Palodex Group Oy
Jouni Karkinen
Regulatory Manager
Nahkelantie 160
FI-04300 Tuusula,
FINLAND

Re: K162799
Trade/Device Name: Cliniview
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 14, 2017
Received: March 20, 2017

Dear Jouni Karkinen:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162799

Device Name
Cliniview

Indications for Use *(Describe)*
Cliniview software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

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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510(k) SUMMARY

Cliniview

Submitter Information

Palodex Group Oy
Nahkelantie 160
FI-04300 Tuusula
Finland

Contact Person: Jouni Karkinen
Email: regulatory@palodex.com
Telephone Number: +358 10 270 2000
Fax Number: +358 10 270 2230

Date Prepared: March 14, 2017

Device Name

Proprietary Name: Cliniview
Common name: Dental imaging device
Classification Name: System, Image Processing, Radiological
CFR Number: 892.2050
Device Class: 2
Product Code: LLZ

Predicate Device

Proprietary Name: VixWin Platinum
510k Number: K141451
Common Name: Dental imaging device
Classification Name: System, Image Processing, Radiological
CFR Number: 892.2050
Device Class: 2
Product Code: LLZ

Predicate Device

Proprietary Name: DEXIS Software
510k Number: K140445
Common Name: Dental imaging device

Classification Name:	System, Image Processing, Radiological
CFR Number:	892.2050
Device Class:	2
Product Code:	LLZ

Predicate Device

Proprietary Name:	Romexis
510k Number:	K140713
Common Name:	Dental imaging device
Classification Name:	System, Image Processing, Radiological
CFR Number:	892.2050
Device Class:	2
Product Code:	LLZ

Description of Device

Cliniview software has the functionality which compares with the functionality provided by VixWin Platinum predicate cleared under K141451, the DEXIS Software predicate cleared under K140445 and the Romexis predicate cleared under K140713.

Scanora software is equal with the Cliniview software with branding labeling differences. Scanora is product name for Soredex brand imaging products whereas Cliniview is for Instrumentarium Dental imaging products. There is no difference in design. Cliniview 11 equals Scanora 6. This submission discusses about Cliniview software covering Scanora software at the same time.

Cliniview software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

The types of images handled by Cliniview include, for example, panoramic, cephalometric, CBCT, intra-oral, and color photographs. Images can be viewed from a workstation, a mobile application or using a web browser. The Mobile Application is not intended for diagnostic use.

Cliniview image acquisition supports imaging plates, intraoral sensors and digital X-ray imaging devices. Images can also be imported from other digital sources. Cliniview stores images and patient information in the SQL database and provides tools for image archiving. Cliniview has interfaces to 3rd party systems through the proprietary dental practice management system interface and DICOM standard interface.

The main features of the Cliniview software include patient management, image acquisition, patient and image data storage, image viewing of 2D images and processing and enhancement of images.

Cliniview software can be utilized either locally or over a networked environment. If Cliniview is installed on several computers, the patient and image database can be shared among them and used from different workstations.

Shelf-life is not applicable to Cliniview software, because of no likelihood of time-dependent product degradation. Performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.

Indications for Use

Cliniview software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.

Technological Characteristics

The following table 7-1 gives technological characteristics between the proposed Cliniview software and the cleared version of the VixWin Platinum Software (K141451), the DEXIS Software (K140445) and the Romexis (K140713).

Table 7-1

Feature	**VixWin Platinum (K141451) (Predicate)**	**DEXIS Software (K140445) (Predicate)**	**Romexis (K140713) (Predicate)**	**Cliniview (Proposed)**
Indication for Use / Intended Use	VixWin Platinum is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.	The DEXIS Software is a software program for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement and saving of X-ray digital images from digital imaging systems. It can also handle other types of images acquired by digitizing film with a flatbed scanner, or color images from intra-oral and extra-oral dental cameras.	Planmeca Romexis is a medical imaging software, and is intended for use in dental and medical care as a tool for displaying and visualizing dental and medical 2D and 3D image files from imaging devices, such as projection radiography and CBCT. It is intended to retrieve, process, render, diagnose, review, store, print, and distribute images.	Cliniview software program is indicated for general dental and maxillofacial diagnostic imaging. It controls capture, display, enhancement, and saving of digital images from various digital imaging systems. It stores and communicates these images within the system or across computer systems at distributed locations.
Implementation	Software only	Software only	Software only	Software only

Feature	**VixWin Platinum (K141451) (Predicate)**	**DEXIS Software (K140445) (Predicate)**	**Romexis (K140713) (Predicate)**	**Cliniview (Proposed)**
Overall Functionality	The imaging program for X-ray and color images	The imaging program for X-ray and color images	The imaging software for digital imaging devices and video cameras	The imaging program for X-ray and color images
Image Processing Functionality	Enhancement, annotation, measurement, import/export and printing.	Enhancement, annotation, measurement, import/export and printing.	Enhancement and archiving images.	Enhancement, annotation, measurement, import/export and printing.
Host Platform	PC	PC & Apple Mac	PC & Apple Mac	PC
Host Operating System	Windows 7 Professional (32/64-bit) Windows 8 Professional (32/64-bit) Windows XP Professional (32/64-bit) Windows Vista Business (32/64-bit) Windows Server 2003 Windows Server 2008	Windows XP Professional SP3 (32 bit) Windows Vista Business SP2 (32 bit) Windows 7 Professional, Ultimate, Enterprise, all SP1 (32 and 64 bit) Windows Server 2003 Windows Server 2008	Windows 7 Pro (32 or 64 bit) Windows 8.1 Pro (32 or 64 bit) Windows 10 (64 bit) Windows 2008 Server (64 bit) Windows 2012 Server (64 bit) Mac OS X (Intel)	Windows 7 Professional/ Ultimate/ Enterprise SP1 (32 or 64-bit) Windows 8/8.1 Professional/ Enterprise (32 or 64-bit) Windows 10 Windows Server 2012/2012R2
Host RAM	1024 MB minimum, 2048 MB recommended	Workstations: 1 GB or higher Servers: 1 GB or higher	Workstations: 3/ 8 GB Servers: 3/ 8 GB	4 GB
Host magnetic storage	30 GB minimum, 200 GB recommended	Workstations: 80 GB or larger Servers: 120 GB or larger	Workstation: 80 GB Servers: 2 x 500 GB	8 GB free space 10 GB hard disk database
Host floppy drives	Not required	Not required	Not required	Not required
Installation Media	DVD or Network	CD/DVD, USB and network download	DVD ROM or R/W drive	DVD or Network

Feature	VixWin Platinum (K141451) (Predicate)	DEXIS Software (K140445) (Predicate)	Romexis (K140713) (Predicate)	Cliniview (Proposed)
Host Processor Speed	Pentium 4 2.0 GHz min, Pentium 4 3.2 GHz recommended	Windows: Intel® Pentium® 4 or higher	Processor Intel Core 2 Duo 2 GHz or better	Intel Core i3 or better
Host Monitor Size	SVGA with 0.25/0.26 dot pitch	Windows: SVGA, XGA recommended	Full HD	19" or larger recommended
Display resolution	1024 x 768 24 bit true color min, 32 bit true color recommended	Windows: 800 x 600 with a minimum of .25 dot pitch Mac: 1280 x 768 pixels minimum	1280 x 1024 (1920x1080 recommended)	1280 x 1024 resolution 24-bit color Monitor must provide a brightness of 300cd/m2 for rooms < 1000 lux Monitor must provide a minimum contrast ratio of 100:1
User Display Preferences	Yes	Yes	Yes	Yes
USB and S Video support	USB and S Video support	USB and S Video support	USB support	USB and S Video support
Receive Images from other Systems	Yes	Yes	Yes	Yes
Images Displayed	2D dental X-rays, intraoral and extraoral images	2D dental X-rays, intraoral and extraoral Images	2D and 3D dental X-rays, intraoral and extraoral images	2D dental X-rays, intraoral and extraoral images
Database	Images and related data are stored in the VixWin Platinum database or remotely accessible database in the network.	Images and metadata are stored in the DEXIS database.	Images and metadata are stored in the Romexis database.	Images and related data are stored in the Cliniview database or remotely accessible database in the network.
Image Acquisition	Imaging plate scanners, intraoral sensors, intra oral video camera,	Digitizing film with a flatbed scanner, or color images from intra-oral and extra-oral dental cameras	Imaging plate scanners, intraoral sensors, intra oral video camera,	Imaging plate scanners, intraoral sensors, intra oral video camera,

Feature	**VixWin Platinum (K141451) (Predicate)**	**DEXIS Software (K140445) (Predicate)**	**Romexis (K140713) (Predicate)**	**Cliniview (Proposed)**
	digital extra oral x-ray devices, various image file formats		digital extra oral x-ray devices, various image file formats	digital extra oral x-ray devices, various image file formats
Viewers / Modes	Panoramic, Cephalometric, CBCT, Intra-oral, color photographs	Panoramic, Cephalometric, CBCT, Intra-oral, color photographs	Intraoral Panoramic Cephalometric 2D linear tomography Photos Stack images 3D CBCT 3D photo 3D surface scan	Panoramic, Cephalometric, CBCT, Intra-oral, color photographs
Implant Planning	Not included	Implant library, which can be used for implant planning searching for implants.	Optional implant library, which can be used for implant planning, searching for implants, creating new implants, modifying, adding and replacing implants in the plan.	Implant library, which can be used for implant planning, searching for implants, creating new implants, modifying, adding and replacing implants in the plan.
Supports Mobile Application	No	No	iPad and iPhone application	iPad application

Non clinical performance data

The safety and effectiveness of Cliniview software including Mobile app has been evaluated via internal in-house design verification and validation testing and via conformance to international standards.

As part of verification and validation conformance IEC 62304 and ISO 14971, design validation, unit testing, code reviews, integration testing and system verification testing was ensured for Cliniview.

Substantial Equivalence

There are no significant differences between the proposed Cliniview software and the predicate VixWin Platinum, DEXIS Software and Romexis devices. Minor differences, as described in Table 7-1, between proposed the Cliniview software and the predicate devices do not significantly affect substantial equivalence of the device.

The proposed device is substantially equivalent to the predicate devices based on the indications for use, technological characteristics and theory of operations. Minor differences between proposed Cliniview software and the predicate devices relating to required hardware, and operating system functionality do not significantly affect safety and effectiveness. In summary, Cliniview software described in this submission is substantially equivalent to the Vixwin Platinum software cleared under K141451, the DEXIS Software cleared under K140445 and the Romexis cleared under K140713 and satisfies all criteria of substantial equivalence.