MAR 2 0 2014

K133231
Page 1 of 4

PALODEX GROUP

PaloDEx Group Oy

www.palodexgroup.com

Street address
Nahkelantie 160
04300 Tuusula
Finland

Postal address
PO Box 64
FI-04301 Tuusula
Finland

Phone
+358 10 270 2000

Fax
+358 9 851 4048

VAT
FI19774137

BI code
1977413-7

Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

510(k) Summary

Date: October 10, 2013, revised February 4, 2014

Manufacturer:

PaloDEx Group Oy
Nahkelantie 160
Tuusula, Finland 04300

Tel: +358 10 270 2000
Fax: +358 9 701 5263

Contact person: Mr. Terho Turkumäki, Tel +358 50 320 9113

Trade Name:
DIGORA® Optime

Common Name:
Imaging plate reader

Classification Name:
872.1800 Extraoral source x-ray system. Product Code MUH.

Description:

DIGORA® Optime (DXR-60) is a digital radiography system for intra oral imaging plates located in disposable bags. The system may be used with all x-ray equipment which is designed for intra oral radiography. The image is recorded on reusable imaging plate which substitutes for conventional x-ray film or digital sensor. The x-ray energy absorbed in the imaging plate remains stored as a latent image. When fed to the device the stored energy is released as an optical emission proportional to the stored energy when the imaging plate is stimulated pixel by pixel by a scanning laser. An optical system collects the emission for photo electronic system, which converts the emission to digital electronic signals. These signals are processed in a computer system which formats and stores the signals.

Further image processing, display and achieving are carried out with auxiliary software.

Indications for Use:

The DIGORA® Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

Intended Use:

SOREDEX® DIGORA® Optime system is intended to be used only by dentist and other qualified dental professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull.

PALODEX GROUP

PaloDEx Group Oy

www.palodexgroup.com

Street address
Nahkelantie 160
04300 Tuusula
Finland

Postal address
P.O Box 64
FI-04301 Tuusula
Finland

Phone
+358 10 270 2000

Fax
+358 9 851 4048

VAT
FI19774137

BI code
1977413-7

Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

Summary of Technological Characteristics:

DIGORA® Optime (DXR-60) is substantially equivalent in design, composition and function to the current DIGORA Optime unit (K041050).

Concept		**Proposed DXR-60**	**Predicate DXR-50** (Cleared Under K041050)
1.	Theoretical resolution	16,7 lp/mm	12,5 lp/mm
2.	Image data bit depth	14-bit	14-bit
3.	Image scanning time (size 2)	6,8 s	5,1 s
4.	Pixel size (selectable)	30 µm (Super resolution) 60 µm (High resolution)	40 µm (Super resolution) 64 µm (High resolution)
5.	Imaging plates	0,1,2,3	0,1,2,3
6.	Operating voltage	24 VDC (External PSU 100-250 V, 50/60Hz)	24 VDC (External PSU 100-250 V, 50/60Hz)
7.	Laser safety classification	Class 1 laser product EN 60825-1:2007	Class 1 laser product EN 60825-1:2007
8.	Interface	Ethernet RJ-45 10/100 Mbs LAN	Ethernet RJ-45 10/100 Mbs LAN
9.	Operating environment	+10°C - +40°C, 30 – 90 RH%, 700 – 1060 mbar	+10°C - +40°C, 30 – 90 RH%, 700 – 1060 mbar
10.	Storage / Transportation environment	-10°C – +50°C, 0 – 90 RH%, 500 – 1080 mbar	-10°C – +50°C, 0 – 90 RH%, 500 – 1080 mbar
11.	IEC60601-1 classification	Class 2	Class 1
12.	IP classification	IPX0	IPX0
13.	Applied part	None	None
14.	Dimensions	152 mm x 227 mm x 308 mm (6.0 x 8.9 x 12.1 inches)	191 mm x 221 mm x 394 mm (7.5 x 8.7 x 15.5 inches)
15.	Indications for use	The DIGORA® Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.	The DIGORA® Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.
16.	Intended use	SOREDEX® DIGORA® Optime system is intended to be used only by dentist and other qualified dental	The DIGORA Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images

PaloDEx Group Oy

www.palodexgroup.com

Street address
Nahkelantie 160
04300 Tuusula
Finland

Postal address
P.O Box 64
FI-04301 Tuusula
Finland

Phone
+358 10 270 2000

Fax
+358 9 851 4048

VAT
FI19774137

BI code
1977413-7

Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

		professionals to process x-ray images exposed to the imaging plates from the intraoral complex of the skull.	stored in imaging plate recording media.
17.	Weight	3,5 kg (7.7 lb)	7 kg (15.5lb)

In DXR-60, representative machined aluminium components in the predicate device DXR-50 have been replaced by equivalent plastic components. This has been done as part of device evolution to support modern manufacturing techniques. The most significant components that have been modified to plastic are device chassis, plate carrier and the door. All replaced components provide equivalent functionality to the predicate device DXR-50. This functionality has undergone design verification / validation, and system testing where applicable to ensure that the material change has no impact on safety, effectiveness, and overall performance of the device including image quality and expected lifetime of the device

In DXR-60, the User interface Control Panel has been modified from DXR-50 (the predicate device) for better visual communication and usability. In addition to relocating the power and start buttons, the modifications to the User Interface control panel consist of lighted numeric LED's and other relevant symbols which depict plate positioning, device status and error codes. It has been verified and validated that this change does not affect safety or efficacy of the device.

DXR-60 has Comfort Occlusal 4C image processing ability. In DXR-60 this ability means that two size 3 plates can be stitched together to form a larger image for an occlusal view. Image plates are processes and supplied separately to the user, and also stitched together to form a single Comfort Occlusal 4C projection image. This makes this feature safe. It has been verified and validated that this feature does not affect safety or effectiveness of a device.

The results of the design verification and validation demonstrated that modifications did not affect safety and efficacy of the device or raise any new questions of safety or efficacy.

Non-clinical Test Data:

Testing was conducted to all applicable requirements according to FDA's guidance ""Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices".

Comparison between DIGORA® Optime (DXR-60) and the predicate device was performed with the same technical phantoms. Anthropomorphic phantom images of periapical and bitewing views were provided to demonstrate the system is capable of providing diagnostic-quality images. Anthropomorphic phantom images were deemed appropriate instead of human patient images because the primary target anatomy does not involve moving tissue or soft tissues of similar contrast.

Validations have been performed successfully to ensure the safety and effectiveness of the DIGORA® Optime (DXR-60) system.

Clinical Test Data:

Clinical testing was not deemed necessary on DIGORA® Optime (DXR-60) device.

K133231
Page 4 of 4

PALODEX GROUP

PaloDEx Group Oy

www.palodexgroup.com

Street address
Nahkelantie 160
04300 Tuusula
Finland

Postal address
P.O. Box 64
FI-04301 Tuusula
Finland

Phone
+358 10 270 2000

Fax
+358 9 851 4048

VAT
FI19774137

BI code
1977413-7

Bank
Nordea Bank
SWIFT NDEAFIHH
Account
FI9015963000046864

Conclusion:

Based upon the similar technological/performance characteristics to the predicate device and the successful validation of the DIGORA Optime (K041050), the clinical performance of the DIGORA® Optime (DXR-60) is deemed to be substantially equivalent to the predicate device.

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

March 20, 2014

Instrumentarium Dental, PaloDEx Group Oy
% Mr. Terho Turkumaki
Quality & Regulatory Manager
Nahkelantie 160
Tuusula, 04300
FINLAND

Re: K133231
Trade/Device Name: DIGORA® Optime
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 17, 2014
Received: February 19, 2014

Dear Mr. Turkumaki:

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 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. 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,

for

Janine M. Morris
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)*
K133231

Device Name
DIGORA® Optime

Indications for Use *(Describe)*
The DIGORA® Optime imaging system is indicated for capturing, digitization and processing of intra oral x-ray images stored in imaging plate recording media.

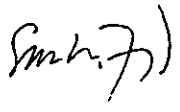
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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."