510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date:

APPLICANT RAY Co.,Ltd

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Device Name
Trade/Proprietary Name : RAYSCAN α – Expert
Common Name: Dental panoramic and cephalometric X-ray system

Classification
Extraoral source dental X-ray system (21 CFR 872.1800)
Class : II
Product code : MUH
Panel : Radiology

Predicate device
Orthophos XG^{Plus} DS/Ceph Dental X-ray system(K033073)

Description
RAYSCAN α- Expert is designed for panoramic scanning of teeth, jaw and oral cavity, used to create and control the X-ray beam. And as a dental digital panoramic X-ray system with X-ray located on outer part of the oral cavity, includes the Cephalometric scanning function, as an option, for acquiring images of the head.
RAYSCAN α- Expert offers digital imaging with or without the optional cephalometric attachment.
The system includes processing, and archiving "SMARTDent "software(Optional)

Indication for use
The RAYSCAN α- Expert Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Statement of Substantial Equivalence

Parameter		RAYSCAN α–Expert RAY Co.,Ltd	Orthophos XG^{Plus} DS/Ceph K033073
Common name		Dental panoramic and cephalometric X-ray system	Dental panoramic and cephalometric X-ray system
Indication for use		The RAYSCAN α- Expert Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.	The Orthophos XG^{Plus} DS/Ceph Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.
Mode of Operation		Continuous operation with intermittent, stated permissible loading	Continuous operation with intermittent load
Performance Specification		Panoramic Cephalometric(optional)	Panoramic Cephalometric(optional)
Imaging modality		Digital only	Digital only
Exam mode	PANO	Normal Pedodontics TMJ Sinus	Standard panorama Standard panorama without ascending branches Pediatric program Lateral Axial Sinus Program for posterior teeth
	Ceph	PA,AP Lateral SMV Carpus Reverse Town's Waters	PA AP Carpus
	Optional		TSA(Transversal layers based on wide-beam tomography)
Detector Type		Pano : Flat panel X-ray sensor Ceph : Flat panel X-ray sensor	Pano : CCD X-ray sensor Ceph : CCD X-ray sensor
Control Panel		Touch monitor(Panel)	Easy Pad(Touch type)
Main Component		Ceph Apparatus	Ceph Apparatus
		Vertical Carriage	Vertical Carriage
		Rotator	Rotator
		X-RAY Generator	X-ray Generator
		X-ray tube	X-ray tube
		High Frequency Generator	High Frequency Generator
		Column	Column
		Touch monitor (panal)	Easy Pad(Touch type)

	Detector(Panoramic, Cephalometric)	Detector(Panoramic, Cephalometric)
	Chinrest	Chinrest
	Head rest	Head rest
	Automatic Collimator	Collimator
	Exposure switch	Exposure switch
	Emergency stop switch	Emergency stop switch
Automatic Collimator	Yes	Yes
Accessories	Bite block	Bite block
	Chinrest(Patient support of the stand type) Chinrest(TMJ, Sinus and etc:)	Chinrest (Patient support of the stand type)
	Head rest	Head rest (included temple support)
	X-ray push button with extensible cable	X-ray push button
	Earload	Earplugs with holders
	Nasal bar	Nose support
	Remote controller(Optional)	Remote controller(Optional)
Rated power	110-240 V~, 50 / 60 Hz, 2.3kVA	100-120 V, 220-240 V, 50/60Hz, 2.8kW
Class	Class I with type B applied parts according to IEC 60601-1	Class I with type B applied parts according to IEC 60601-1
Focal size	0.5mm	0.5mm
X-ray Voltage	60~90kVp	60~90kVp
X-ray Current	4~17mA	3~16mA
Total Filtration	2.6 ㎜ Al equivalent	2.5 mm Al equivalent
Detector Pixel size	Pano : 100 ㎛ Ceph : 150 ㎛	Pano : 27 ㎛ Ceph : 27 ㎛
Magnification	Pano :1.31 Ceph :1.13	Pano : 1.25 Ceph : 1.25
Scan time	Pano : 14sec Ceph : 0.3sec-3sec	Pano : 14.2sec Pano(Quickshot) : 9.1sec Ceph : 9.14sec Ceph(Quickshot) : 4.7sec
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
PC technical Specifications (Requirements for PC system)	- OS : Windows 7, 32Bit - CPU : Intel Dual core and over - RAM : 4GB and over - HDD : 500GB and over - Network : Gigabit Ethernet - Display : 32 bit color display - Resolution : 1366x768 and over	- OS : Windows 2000 Workstation , Windows XP Professional Workstation or Vista - RAM: min. 256 MB - HDD: > 4 GB/database > 50 MB/SIDEXIS installation - Network : 10/100 MBit Ethernet - Resolution : 1024x768 and over
Dimension	Panoramic : 1,118mm x 1,481mm x 2,296mm (WxDxH) Panoramic+Cephalostic(optional) : 1,672mm x 1,481mm x 2,296mm (WxDxH)	Panoramic : 1,042mm x 1,371mm x x 2,249mm (WxDxH) Panoramic+Cephalostic(optional) : 1,955mm x 1,371mm x x 2,249mm (WxDxH)

Weight	Panoramic : 147kg(324lb) Panoramic+Cephalostic(optional) : 164kg(361lb)	Panoramic : 120kg(264lb) Panoramic+Cephalostic(optional) : 141kg(310lb)
Type of installation	Wall or floor mount	Wall or floor mount
Patient position	Standing / Wheelchair	Standing / Wheelchair
Applicable Standards	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-1 IEC 60601-1-3 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32 IEC 60601-1-2
Certificate Product	CE0120(MDD93/42/EEC)	CE0086(MDD93/42/EEC), FDA,SFDA

RAYSCAN α- Expert have the same indication for use as the predicate devices, It shares the same technological characteristics as the predicate devices, Minor technological differences do not raise any new questions regarding safety or effectiveness of the devices.

Safety and Effectiveness Information

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, IEC 60601-1-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2.
Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" were performed.

All test results were satisfactory.

Conclusions

Based on a comparison of intended use, indications, constructions, construction materials, principal of Operation, features and technical data, the RAYSCAN α- Expert system is safe and effective to perform its intended use as well as 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 15, 2013

Ray, Co., Ltd.
% Mr. Andrew Paeng
Consultant
8920 Wilshire Blvd., Suite 603
BEVERLY HILLS CA 90211

Re: K122918
Trade/Device Name: RAYSCAN α-Expert
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: January 14, 2013
Received: February 06, 2013

Dear Mr. Paeng:

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,

for

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

Enclosure

Indications for Use

510(k) Number (if known): K122918

Device Name: RAYSCAN α- Expert

Indications for Use:

The RAYSCAN α- Expert Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K122918