Special 510(k) Summary

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

Date:

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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

RAYSCAN α–Expert (K122918)

Description

Modified 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.

The modifications are as following:

- *Hardware: Added option CEPH sensor (Scan type). In addition to the one-shot type CEPH sensor of original device (K122918), the modified device offers an additional Scan type CEPH sensor.*

- *Updated Software including:*
  - *Additional protocol for new CEPH sensor (Scan type): Lateral wide*
  - *Additional PANO protocols: Segmentation (Individual Tooth), Bitewing, and Orthogonal*

RAYSCAN α- Expert offers digital imaging with or without the optional One-shot type & Scan type cephalometric attachment.

Detector Options:

Base: RAYSCAN α-P: PANO
Option: RAYSCAN α-OC: PANO+One-shot CEPH
Option: RAYSCAN α-SC: PANO+SCAN CEPH

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 [Modified]	RAYSCANα-Expert [K122918]	Remarks
Common Name	Dental panoramic and cephalometric X-ray system	Dental panoramic and cephalometric X-ray system	Same
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.	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.	Same
Performance Specification	Panoramic Cephalometric(optional) - One_shot type - *Scan type*	Panoramic Cephalometric(optional) -One_shot type	Additional Scan type Cephalometric (Optional)
Detector type	α-OC : PANO+One-shot CEPH(option) α -P : PANO *α -SC: PANO+SCAN CEPH(option)*	α-OC :PANO+One-shotCEPH(option) α -P : PANO	Additional Scan type Cephalometric (Optional)
Detector Type	Pano : Flat panel X-ray sensor	Pano : Flat panel X-ray sensor	
	Ceph(Optional) - Flat panel X-ray sensor [One-shot type] - *CdTe Direct flat panel sensor[Scan type]*	Ceph(Optional) - Flat panel X-ray sensor	Additional Scan type Cephalometric (Optional)
Focal size	0.5mm	0.5mm	Same
X-ray Voltage	60~90kVp	60~90kVp	Same
X-ray Current	4~17mA	4~17mA	Same
Total Filtration	2.6 ㎜ Al equivalent	2.6 ㎜ Al equivalent	Same
Magnification	Pano : 1.31	Pano : 1.31	Same
	Ceph[One-shot type] : 1.13	Ceph[One-shot type] : 1.13	Same

	Ceph[Scan type] : 1.11	-	Additional specification of Scan type Cephalometric (Optional)
Scan time	Pano : 14sec	Pano : 14sec	Same
	Ceph[One-shot type] : 0.3sec~3.0sec	Ceph : 0.3sec~3.0sec	Same
	Ceph[Scan type] : below 18sec	-	Additional specification of Scan type Cephalometric (Optional)
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	Same
Certificate Product	CE0120(MDD93/42/EEC)	CE0120(MDD93/42/EEC)	Same

Safety details, for instance the non-clinical performance, in regards to intended use, safety characteristics, PANORAMA sensor (Detector) and One-shot CEPH sensor(Detector) are equivalent. The only difference is the additional option of Scan type CEPH sensor.
The safety & effectiveness reports for the added Scan type cephalometric sensor is provided separately.

Remaining sensors are the same, the non-clinical & clinical considerations thereof are also equivalent, and the report regarding non-clinical & clinical consideration for the added Scan CEPH sensor is provided separately.
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 device.

Based on the non-clinical and clinical consideration and the outcome of an expert review of image comparisons for both devices, new RAYSCAN α-Expert is substantially equivalent, in terms of safety and effectiveness, with RAYSCAN α- Expert[K122918].

Safety and Effectiveness Information

Software verification testing and validation testing was performed to confirm that the modified device performed as intended and that changes made to the hardware and software had no adverse impact on the functionality of the system.
All tests met requirements demonstrating that the modified device performed as expected.

Electrical, mechanical, environmental safety and performance testing according to standards 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 the 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 are 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

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Ray Co., Ltd.
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November 1, 2013

Re: K131693
Trade/Device Name: RAYSCAN a-Expert
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 1, 2013
Received: October 11, 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 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" (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 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,

Michael D. O'Hara

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): K131693

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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael D. O'Hara

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiolgical Health

510(k) ____K131693_____