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 3D
Common Name: Dental panoramic/tomography and cephalometric x-ray system

Classification

x-ray, tomography, computed, dental (21 CFR 892.1750)
Class : II
Product code : OAS
Panel : Radiology

Predicate device

RAYSCAN α-Expert 3D(K122981)

Description

RAYSCAN α–Expert 3D is a 3D computed tomography for scanning hard tissues such as bones and teeth. By rotating the c-arm that include the high voltage generator all-in-one x-ray tube and a detector on each end, a CBCT image of whole dentomaxillofacial is attained by recombining data from the same level that are scanned from different angles.

Panoramic image scanning function for attaining images of the entire or segmental teeth and cephalometric scanning option (One shot type & Scan type) for attaining the cephalic images are included. It allows to choose from two different types of CEPH detectors:

Detector Options:

Base: RAYSCAN α-3D: CT+PANO

Option: RAYSCAN α-Multi 3D: CT+PANO+One-shot CEPH

Option: RAYSCAN α-SM3D: CT+PANO+SCAN CEPH

SMARTDent software for processing and archiving is optional.

Indication for use

RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images.

The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations.

2D Image is obtained using the standard narrow beam technique.

Statement of Substantial Equivalence

Parameter	RAYSCAN α-Expert 3D [Modified]	RAYSCANα-Expert 3D [K122981]
Common Name	Dental panoramic/tomography and cephalometric x-ray system	Dental panoramic/tomography and cephalometric x-ray system
Indications for use	RAYSCAN α-Expert 3D panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique.	RAYSCAN α-Expert 3D panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillo-facial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique.
3D technology	CBCT Cone beam Computed Tomography	CBCT Cone beam Computed Tomography
Performance Specification	CBCT Computed tomography Panoramic Cephalometric(optional) - One_shot type *- Scan type*	CBCT Computed tomography Panoramic Cephalometric(optional) -One_shot type
Functional Option	Base α -3D : CT+PANO Option α-Multi 3D: CT+PANO+One-shot CEPH(option) *α -SM3D: CT+PANO+SCAN CEPH(option)*	Base α -3D : CT+PANO Option α-Multi 3D: CT+PANO+One-shot CEPH(option)
Detector Type	Computed Tomography(CT) : Flat panel X-ray sensor	Computed Tomography(CT) : Flat panel X-ray sensor
	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
Focal size	0.5mm	0.5mm
Field of View(CT)	90x90mm	90x90mm

X-ray Voltage	60~90kVp	60~90kVp
X-ray Current	4~17mA	4~17mA
Total Filtration	2.6 ㎜ Al equivalent	2.6 ㎜ Al equivalent
Magnification	CT : 1.39	CT : 1.39
	Pano : 1.31	Pano : 1.31
	Ceph[One-shot type] : 1.13	Ceph[One-shot type] : 1.13
	Ceph[Scan type] : 1.11	-
Scan time	CT : 14sec	CT : 14sec
	Pano : below 14sec	Pano : 14sec
	Ceph[One-shot type] : 0.3sec~3.0sec	Ceph : 0.3sec~3.0sec
	Ceph[Scan type] : below 18sec	-
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 60601-2-44 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 60601-2-44 IEC 60601-1-2
Certificate Product	CE0120(MDD93/42/EEC)	CE0120(MDD93/42/EEC)

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

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 considerations and the outcome of experts review of image comparisons for both devices, new RAYSCAN α-Expert 3D is substantially equivalent, in terms of safety and effectiveness, to the predicate device RAYSCAN α- Expert 3D[K122981].

K131695
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Safety and Effectiveness Information

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, IEC 60601-2-32 and IEC 60601-2-44 was performed, and EMC testing was conducted in accordance with the standard IEC 60601-1-2.

In addition, 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 Operations, features and technical data, the RAYSCAN α–Expert 3D 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

Food and Drug Administration
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Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ray Co., Ltd.
% Mr. Andrew Paeng
Consultant
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SANTA ROSA CA 95405

November 1, 2013

Re: K131695
Trade/Device Name: RAYSCAN a-Expert 3D
Regulation Number: 21 CFR 872.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
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): K131695

Device Name: RAYSCAN α–Expert 3D

Indications For Use:

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2D Image is obtained using the standard narrow beam technique.

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)

Michael D. O'Hara

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostic and Radiological Health

510(k) ____K131695_____