K130443
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510(k) Summary

JUN 14 2013

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

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Designated Agent:	Claude BERTHOIN Denterprise International, IncRF America, Inc. 110 W. Granada Blvd., Suite 207 Ormond Beach, FL 32176 Phone: 800-323-2690 Ext 304 Fax: 386-672-4402
Date Prepared:	February 3, 2012
Trade Name:	I-MAX Touch 3D
Common Name:	Computed Tomography X-Ray System
Classification Name:	X-Ray, Tomography, Computed, Dental
Classification Regulation:	21 CFR 892.1750
Panel:	Dental
Class:	II
Product Code:	OAS
Predicate Devices:	Villa Sistemi Medicali Rotograph EVO 3D (K111152)
Product Description:	The I-MAX Touch 3D is a panoramic x-ray system utilizing digital imaging. It can be equipped with a cephalostat. The device can be equipped with accessories to fulfill different diagnostic needs. The images are acquired by a flat panel detector and are displayed on a monitor; image processing, manipulation, archiving, communication and 3D reconstruction (starting from cross-sectional images taken using CBVT (Cone Beam Volumetric Tomography) technique) are performed using a computer.
Indications for Use:	The I-MAX Touch 3D, panoramic X-ray imaging system with cephalostat, is an extra-oral 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. It also has the capability, using the CBVT technique, to generate dento-maxillofacial

3D images. The device uses a cone shaped X-ray beam projected on a flat panel detector and the examined volume image is reconstructed to be viewed on 3D viewing stations. 2D Images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.

Rationale for Substantial Equivalence: The I-MAX Touch 3D has the same indication for use as the predicate device. It is identical to the predicate device except for the design of some of its external plastic covers and for the control panel. It shares the same technological characteristics as the predicate device. The minor technological and design differences do not raise any new questions regarding safety or effectiveness of the device; both devices are used in the same identical way.

Safety and Effectiveness Information: The device labeling contains operating instructions for safe and effective use of the I-MAX Touch 3D. The software development for this device follows documented processes for software design, verification and validation testing. Final device validation and risk assessment has been conducted to identify potential design hazards that could cause an error or injury based on the use of this device. Appropriate steps have been taken to control all identified risks. The device has been tested for compliance to IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety and its derivatives.

Conclusion: The I-MAX Touch 3D performs the same identical functions in the same environment as the predicate device. It uses the same technology as the predicate device, based on well-known technology. It is as safe and effective as the predicate device. We believe it does not introduce any new potential safety risks and is substantially equivalent and identical 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

June 14, 2013

Owandy
% Mr. Claude Berthoin
110 E. Granada Blvd.
Suite 207
ORMOND BEACH, FL 32176

Re: K130443
Trade/Device Name: I-MAX Touch 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: March 26, 2013
Received: March 27, 2013

Dear Mr. Berthoin:

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.

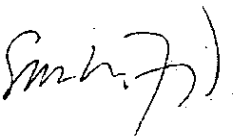
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

510(k) Number (if known): K130443

Device Name: I-MAX Touch 3D

Indications for Use:

I-MAX Touch 3D, panoramic X-ray imaging system with cephalostat, is an extra-oral source Xray 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. It also has the capability, using the CBVT technique, to generate dentomaxillofacial 3D images. The device uses a cone shaped X-ray beam projected on a flat panel detector; the examined volume image is reconstructed to be viewed on 3D viewing stations. 2D Images are obtained using the standard narrow beam technique. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals

Prescription Use ___✓___ 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) K130443