K123332

510K Summary

Summary Prepared on : 07.17.2013

JUL 18 2013

1. General Information of Submitter and Correspondent

Applicant	:	RF Co. Ltd
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Contact Person	:	Daisuke Tanaka
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Email	:	dt.os@rfsys.biz

3. Trade/Proprietary Name:

NAOMI-CT

4. Common Name:

Dental Computed Tomography X-ray System

5. Classification Name

Dental Computed Tomography X-ray System
(21 CFR 892.1750, Product Code OAS, Class 2)

6. Device Description

NAOMI-CT is a diagnostic x-ray imaging system, which consists of computed tomography x-ray system and panoramic x-ray system. It is used for detecting oral and maxillofacial abnormalities and diseases of patients of all ages and gender.

NAOMI-CT achieves above by utilizing CMOS and CCD sensors equipped in the system, and captures 3D computed tomography scanned image and 2D Panoramic X-ray image of the oral and maxillofacial anatomy on a real time basis by computed reconstruction of x-ray image data from the same axial plane taken at different angles.

7. Indications for Use

The NAOMI-CT is used to take three- and two-dimensional x-ray images for the detection of dental abnormalities for a purpose of examination and diagnosis of diseases of the teeth, jaw, and oral structures.

8. Predicate Device

TAKARA BELMONT CORP. : BEL-CAT Dental Cone Beam CT (K101181)

E-WOO TECHNOLOGY : E-WOO Dental Imaging System Model EPX-Impla (K070658)

9. Substantial Equivalence

RF Co. Ltd perceives that NAOMI-CT is substantially equivalent to BEL-CAT Dental Cone Beam CT of Takara Belmont Corp. and E-Woo Dental Imaging System Model EPX-Impla of E-Woo Technology.

The indications for use, performance, safety characteristics and energy source are same for NAOMI-CT and the predicate devices. The primary difference is the cosmetic, structure and component used only.

10. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1, 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 standard IEC 60601-1-2. For clinical and non-clinical considerations, the testing was conducted in accordance with FDA's Guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. Additionally, High Contrast Resolution, Low Contrast Resolution, Artifact and Dosimetry Evaluation were also performed. All test results were satisfactory.

Non-clinical & Clinical considerations in this submission prove that NAOMI-CT and predicate devices share the same qualities and characteristics. All the results were satisfactory to indicate the equivalence of NAOMI-CT to the predicates. .

11. Statement of Compliance with Federal X-ray Performance Standards

NAOMI-CT is in compliance with the necessary Federal X-ray performance standards.

12. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR 807 and based on the information provided in this premarket notification, RF Co. Ltd assures that NAOMI-CT is as safe and effective as the predicate devices as described in this submission, and concludes that NAOMI-CT is substantially equivalent to the already marketed devices.

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

July 18, 2013

RF Co. Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
951 Starbuck Streeet, Unit J
FULLERTON CA 92833

Re: K123332
Trade/Device Name: NAOMI-CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: June 13, 2013
Received: June 17, 2013

Dear Ms. Chung:

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.

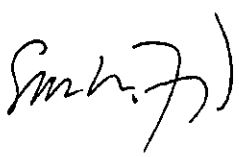
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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): K123332

Device Name: NAOMI-CT

Indications for Use:

The NAOMI-CT is used to take three- and two-dimensional x- ray images for the detection of dental abnormalities for a purpose of examination and diagnosis of diseases of the teeth, jaw, and oral structures..

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) K123332