510(k) Summary K063121

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

Date: September 4, 2006 JAN 11 2007

1. Company and Correspondent making the submission:

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Contact – Yong Jin Park / Engineer
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2. Device :

Trade/proprietary name	: Portable X-Ray System/PORT-X II
Common Name	: Portable X-Ray System
Classification Name	: Extraoral source x-ray system

3. Predicate Devices :

Manufacturer	: Aribex, Inc.
Device	: NOMAD Dental X-ray System
510(k) Number	: K051795(Decision Date - Jul. 14. 2005)

4. Classifications Names & Citations :

21CFR 872.1800, EHD - Extraoral source x-ray system, Class 2

5. Description :

5.1 General

PORT-X II is a portable dental X-ray system that operates on 22.2VDC supplied by a rechargeable Li-Polymer battery pack. The X-ray tubehead, X-ray controls, and power

source are assembled into a single hand-held enclosure. The package includes spare batteries, a battery charger.

5.2 Outline

This equipment generates and controls X-ray in order to diagnose of hand, tooth and jaw.

It is composed of X-ray generator, controller and beam limiting device.

Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor).

5.3 Operating Principle

Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor).

5.4 Features

- Leakage Current of External Body should be satisfied with the Leakage Current Requirement of IEC 60601-1.
- When the Radiation is shooting, buzzer makes sound. And then, when the shooing is Stopped, the sound is turned off.
- X-Ray Shooting Controller: <Dead Man Type>

  Without opening Dead Man Controller, shooting X-Ray and continuous shooting should be not operated.

6. Indication for use :

The PORT-X II Portable X-Ray system is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

7. Comparison with predicate device :

GENORAY Co., Ltd. believes that the Portable X-Ray System(PORT-X II) is

substantially equivalent to NOMAD Dental X-ray System of Aribex, Inc..

8. Safety, EMC and Performance Data :

The portable x-ray system, PORT-X II, will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32. All required documents and reports will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

EMC testing was conducted by EMC Compliance Co., Ltd. in accordance with Standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification GENORAY Co., Ltd. concludes that the Portable X-Ray System(PORT-X II) is safe and effective and substantially equivalent to predicate devices as described herein.

10. GENORAY Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

GENORAY Co., Ltd.
% Mr. Marc M. Mouser
Senior Project Engineer, Medical Devices
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
CAMAS WA 98607-8542

JAN 11 2007

Re: K063121
Trade/Device Name: Portable X-Ray System/PORT-X II
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: December 22, 2006
Received: December 26, 2006

Dear Mr. Mouser:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K063121

Device Name: Portable X-Ray System/ PORT-X II

Indications for Use:

The PORT-X II Portable X-Ray system is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Seguin
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063121