K082875

EXARO

FEB - 5 2009

Exhibit 5 510(k) Summary

Portable X-Ray System / Model: DXR-1

1. Submitter and US Official Correspondent

Submitter:	EXARO Co., Ltd.
Address:	#1201 World Meridian Venture Center II
	426-5 Gasan-Dong, Gumcheon-Gu
	Seoul, 153-803, Korea
Official Correspondent:	Shin Kuk Yoo, BD Manager
Telephone No.:	801-303-7440 (Ext. 202)
Fax No.:	801-303-7455
Email:	skyone@LSKBioPartners.com

2. Establishment Registration Number The firm will be registered and listed prior to distribution of medical device.

3. Device Information

Proprietary/Trade Name:	Portable X-Ray System (Model: DXR – 1)
Common/Usual Name:	Portable X-Ray System
Classification Name:	Extraoral Source X-Ray System
Product Code:	EHD
Device Class:	Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

Manufacturer:	GENORAY Co., Ltd.
Device Name:	Portable X-Ray System (Model: PORT-X II)
510(k) Number:	K063121 (Decision Date – Jan. 11, 2007)
Classification:	Extraoral Source X-Ray System: EHD, Class II per regulation 21 CFR 872.1800

5. Description of the Device

DXR-1, a portable dental X-ray system, operates on 25.2V DC supplied by a rechargeable Li-Polymer battery pack. The X-ray tubehead, controls and power source

are assembled into a single hand-held enclosure. The package includes a battery charger.

The potable X-ray system, DXR-1, being composed of X-ray generator, controller, and beam limiting device is designed to diagnose tooth and jaw through generated and controlled X-ray. The mechanical principle of DXR-1 starts from the generation of X-ray by high voltage electricity, which in turn penetrates tooth and jaw area after flowing through X-ray tube and produces X-ray images on X-ray receptors (i.e. chemical film or digital sensor)

This device contains a high frequency inverter that converts direct to alternating current, X-ray tubehead, electrical protective devices, and other elements. The DXR-1 produces sharp and clear images and prevents patients and dentists from radiation exposure with utilizing small dose of radiation.

6. Indications for use

The portable X-ray system (Model: DXR – 1) is intended to be used by trained dentists and dental technicians as 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. Safety, EMC and Performance Data

The compliance of DXR-1 will satisfy the applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-1-3, 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.

EMS test was performed by SGS Testing Korea Co., Ltd. for DXR-1 in accordance with Standard EN/IEC 60601-1-2. All test results were complied with the requirements.

8. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

9. Substantial Equivalence Chart

Company	GENORAY Co. Ltd.	EXARO Co., Ltd.
Model	PORT-X II	DXR-1
510(k) No	K063121	Not assigned yet
Energy Source	Rechargeable 22.2V, DC Lithium Polymer battery pack	Rechargeable 25.2V, DC Lithium Polymer Battery pack
Expose Time	0.01-2.0 seconds, 0.01 increments	0.01-1.6 seconds, 0.01 increments
Time Accuracy	±(10%+1ms)	±(10%+1ms)
Heat Capacity	8.5 KHU	8.5 KHU
Power Output	100 W	180 W
mA	2mA fixed	2mA fixed
kVp	60kV fixed	60kV fixed
Focal Spot	0.8 mm	0.8 mm
Wave Form	Constant Potential (DC)	Constant Potential (DC)
Safety, EMC and performance	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32
Source to skin distance	20cm	20cm
Cone Diameter	7cm	6 cm
User Interface	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.
Exposure switch	Control panel and remote controller	Control panel and remote controller
Tubehead Mounting	Yes	Yes
Intended Use	Intended to use by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. It is intended to use for both adult and pediatric subjects.	

10. Conclusion

In reference to the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and the comparison information provided substantial equivalent chart above, the EXARO Co., Ltd., believes that the portable X-ray system (Model: DXR-1) is safe and effective and substantially equivalent to the predicate device (Model: PORT-X II).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

EXARO Co., Ltd.
% Mr. Shin Kuk Yoo
LSK BioPartners, Inc.
215 South State Street, Suite 100B
SALT LAKE CITY UT 84111

Re: K082875
Trade/Device Name: Portable X-Ray System (Model: DXR-1)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD and MUH
Dated: January 29, 2009
Received: February 2, 2009

Dear Mr. Yoo:

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 (PMA), 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 4 Indications for Use

510(k) number (if known): K082875

Device Name: Portable X-Ray System (Model: DXR-1)

Indications for Use:

The Portable X-ray System (Model: DXR-1) is intended to be used by trained dentists and dental technicians as 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 ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080875