K122124

OSSTEM IMPLANT

OSSTEM Implant Co., Ltd.

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Tab E 510K Summary

MAY 16 2013

510K Summary

Portable X-Ray System / Model : EXARO

1. Submitter and US Official Correspondent

Submitter :	OSSTEM Implant Co,.Ltd.
US Official Correspondent. :	HIOSSEN Inc.,
Contact :	Patrick Lim, QA/RA manager.
Telephone No.:	888-678-0001
Fax No.:	267-759-7004
Email:	dtlim@osstem.com

2. Establishment Registration Number
No establishment registration number has been assigned yet,.

3. Device Information

Proprietary/Trade Name:	Portable X-Ray System(Model:EXARO)
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 FCR 872.1800

5. Description of the Device
EXARO, 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, EXARO, 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 EXARO 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 EXARO 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:EXARO) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

7. Safety, EMC and Performance Data
The compliance of EXARO 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 EXARO 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.

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

May 16, 2013

OSSTEM Implant Co., Ltd.
% Mr. Patrick Lim
QA/RA Manager
85 Ben Fairless Drive
FAIRLESS HILLS PA 19030

Re: K122124
Trade/Device Name: Portable X-Ray System (Model: PORT X II)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: December 26, 2012
Received: April 09, 2013

Dear Mr. Lim:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

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Tab D Indications for Use Statement

510(k) Number K 122124

Device Name : Portable X-Ray System (Model:EXARO)

Indication for use : The Portable X-ray System(Model:EXARO) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 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) K122124