DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 3, 2014

Takara Belmont Corporation
% Robert Schiff, Ph. D.
President
Schiff & Company, Inc.
1120 Bloomfiled Ave.
WEST CALDWELL, NJ 07006

Re: K141293
Trade/Device Name: PHOT-X IIs Model 505
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: EHD
Dated: August 1, 2014
Received: August 4, 2014

Dear Dr. Schiff:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141293

Device Name

PHOT-X IIs Model 505

Indications for Use *(Describe)*

PHOT-X IIs Model 505 is a extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with the resultant image recorded on intraoral dental x-ray film or image receptor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary (as required by 807.92)

(1) SUBMITTER : Takara Belmont Corporation

Address : 1-1-2 Chome, Higashi-Shinsaibashi, Chuo-ku

Telephone : 81-6-6213-5945

Contact person : Toshinori Kiyomatsu

Date prepared : April 18, 2014

(2) DEVICE NAME : PHOT-X IIs Model 505

Trade Name : PHOT-X IIs Model 505

Common Name : Dental Periapical X-ray

Classification Name : UNIT, X-RAY, EXTRAORAL WITH TIMER (per 21CFR section 872.1800, Product Code EHD)

(3) PREDICATE DEVICE : Substantial equivalence is based on following legally marketed devices.

Belmont, PHOT-X II Model 303 (K042260)

Progeny, PREVA (K043092)

Sirona, HELIODENT PLUS (K083344)

(4) DESCRIPTION OF THE DEVICE : PHOT-X IIs Model 505 dental x-ray contains; x-ray generating tubehead, control box and supporting device. Package includes Operator's Manual, Installation Manual and Warranty.

(5) INTENDED USE : The PHOT-XIIs MODEL 505 is an extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with the resultant image recorded on intraoral dental x-ray film or image receptor.

(6) COMPARISON WITH PREDICATE DEVICES : Following table is a comparison of our new PHOT-X IIs Model 505 x-ray and predicate devices.

	New Device	Predicate Device		
	BELMONT PHOT-XIIs Model 505	BELMONT PHOT-XII Model 303 (K042260)	Progeny Preva (K043092)	Sirona HELIODENT PLUS (K083344)
Indications for Use	The PHOT-XIIs MODEL 505 is an extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with the resultant image recorded on intraoral dental x-ray film or image receptor.	PHOT-X II MODEL 303 is a extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with the resultant image recorded on intraoral dental x-ray film or image receptor. The design, function and positioning of the x-ray unit is similar to most all other x-ray machines manufactured for this specific purpose over the past thirty years.	The intended use of the Progeny PREVA Extra-Oral X-Ray system is to act as a diagnostic source for radiographic dental imaging:	The HELIODENT Plus is an extraoral X-Ray source System intended to be used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.
A. X-ray Wave Form	DC Constant potential	DC Constant potential	DC Constant potential	DC Constant potential

	New Device	Predicate Device		
	BELMONT PHOT-XIIs Model 505	BELMONT PHOT-XII Model 303 (K042260)	Progeny Preva (K043092)	Sirona HELIODENT PLUS (K083344)
B. Filament	Pre-heating System	Pre-heating System	Pre-heating System	Pre-heating System
C. Focal Point Measurement	0.4 mm	0.7 mm	0.4 mm	0.4 mm
D. Rated tube potential	60 or 70 kV	60 or 70 kV	60, 65 or 70 kV	60 or 70 kV
E. Rated tube current	3 or 6 mA	4 or 7 mA	4, 5, 6 or 7 mA	7 mA
F. Maximum rated tube potential	70 kV	70 kV	70 kV	70 kV
G. Rated line voltage	120 VAC	120 VAC	120 VAC	120 VAC
H. Line voltage range	108 VAC-132 VAC	108 VAC-132 VAC	108 VAC-132 VAC	108 VAC-132 VAC
I. Apparent resistance of supply mains	0.52 Ω	0.48 Ω	0.4 Ω	0.3 Ω
J. Rated line current	10 A at 70kV, 6 mA	10.8A at 70 kV, 7 mA	10 A	10 A at 70 kV, 7 mA
K. Maximum line current	11A at 70kV, 6 mA	12A at 70kV,7 mA	Unknown	Unknown
L. Exposure time	0.01-2.0 sec., 37 steps	0.01-3.2 sec., 23 steps	0.01-2.0 sec	0.01-3.2 sec., 23 steps
M. Timer accuracy	±5 msec. (below 0.1 sec. setting) ±10 msec. (0.1 sec. setting & up)	±5 msec. (below 0.1 sec. setting) ±10 msec. (0.1 sec. setting & up)	5 % ±1 msec	±10 % + 1 msec
N. Inherent filtration	1.7 mmAl Equivalent	1.7 mmAl Equivalent	Unknown	Unknown
O. Added filtration	0.3 mmAl	0.3 mmAl	Unknown	Unknown
P. Minimum filtration permanently in useful beam.	2.0 mmAl Equivalent at 70 kV	2.0 mmAl Equivalent at 70 kV	2.0 mmAl Equivalent at 70 kV	Unknown
Q. Nominal roentgen output 1-Distal end of regular cone 2-Distal end of long cone	1- 4.6 mGy/s ± 40 % (60 kV, 3 mA) 9.1 mGy/s ± 40 % (60 kV, 6 mA) 5.9 mGy/s ± 40 % (70 kV, 3 mA) 11.8 mGy/s ± 40 % (70 kV, 6 mA) 2- 2.0 mGy/s ± 40 % (60 kV, 3 mA) 4.1 mGy/s ± 40 % (60 kV, 6 mA) 2.6 mGy/s ± 40 % (70 kV, 3 mA) 5.2 mGy/s ± 40 % (70 kV, 6 mA)	1- 5.4 mGy/s ± 40 % (60 kV, 4 mA) 9.4 mGy/s ± 40 % (60 kV, 7 mA) 7.1 mGy/s ± 40 % (70 kV, 4 mA) 12.4mGy/s±40% (70kV, 7 mA) 2- 2.4 mGy/s ± 40 % (60 kV, 4 mA) 4.2 mGy/s ± 40 % (60 kV, 7 mA) 3.1 mGy/s ± 40 % (70 kV, 4 mA) 5.5 mGy/s ± 40 % (70 kV, 7 mA)	Unknown	1- 8.5 mGy/s ± 40 % (60 kV, 7 mA) 11 mGy/s ± 40 % (70 kV, 7 mA)
R. Source to skin distance 1-Regular cone 2-Long cone	1-203 mm 2-305 mm	1-203 mm 2-305 mm	1-200 mm 2-300 mm	1-200 mm 2-300 mm
S. Leaking technique factor	70 kV, 697 mAs	70 kV, 494 mAs	70 kV, 1350 mAs	70 kV, 413 mAs
T. Duty cycle	1 : 30	1 : 50	1 : 15	1 : 60
U. Maximum deviation of tube potential and tube current.	±10 kV, ± 2 mA (below 0.1sec. setting) ±5 kV, ±1 mA (0.1 sec. setting & up)	±10 Kv, ± 2 mA (below 0.1sec. setting) ±5 kV, ±1 mA (0.1 sec. setting & up)	±5 % (tube potential) ±1 mA (tube current)	±5 kV (tube potential) ±1.4 mA (tube current)

(7) PERFORMANCE STSTANDARDS APPLIED : AAMI/ANSI ES60601-1, IEC60601-1-2, IEC60601-1-3, IEC60601-1-6, IEC60601-2-65, ISO14971
(Testing for AAMI/ANSI ES60601-1, IEC60601-1-3 and IEC60601-1-6 will be conducted by Intertek, 70 Codman Hill Road, Boxborough, MA 01719 before marketing. Testing for IEC60601-1-2 was conducted by UL Japan Inc. 4383-326 Asama-cho, Ise-shi, Mie-ken 516-0021 JAPAN and confirmed the compliance with the standard.)

(8) CONCLUSION : The PHOT-XIIs Model 505 has the same intended use and technology characteristics as the predicate devices.