SEP - 7 2004

K042260

10. **510(k) Summary** as required by 807.92

(1) SUBMITTER : Belmont Equipment, A Division of Takara Belmont USA, Inc.
Address : 101 Belmont Drive, Somerset, New Jersey 08873
Telephone : 1-800-223-1192, Fax : 1-800-280-7504
Contact person : MR. Masahiro Kanaya
Date prepared : August 4, 2004

(2) DEVICE NAME : PHOT-X II, MODEL 303
Trade Name : PHOT-X II, MODEL 303
Common Name : Dental Periapical X-ray
Classification Name : UNIT, X-RAY, EXTRAORAL WITH TIMER (per 21CFR section 872.1800)

(3) PREDICATE DEVICE : Substantial equivalence is based on following legally marketed devices.
Belmont, MODEL 2001CP (K874238)
Sirona, HELIODENT DS (K960819)
Planmeca, PROSTYLE INTRA (K970975)

(4) DESCRIPTION OF THE DEVICE : PHOT-X II, MODEL 303 dental x-ray contains; control box, wall mounting, adjustable support arm and x-ray generating tubehead. Package includes Operators Manual, Installation Manual and Warrantee.

(5) INTENDED USE : Intended use is for traditional radiographing for diagnostic purposes of patients upper and lower arch teeth.

(6) COMPARISON WITH PREDICATE DEVICES : The following is a comparison of our MODEL 2001CP x-ray, and our new MODEL 303 x-ray.

		MODEL 2001CP	MODEL 303
A.	X-RAY WAVE FORM	DC Constant wave	DC Constant wave
B.	FILAMENT	Pre-heating system	Pre-heating system
C.	CONTROL PANEL LOCATION	Power circuit board at the arm mounting bracket and the control panel cannot be separated.	Power circuit board and control panel have serial communication circuits, and those can be mounted separately.
D.	PRE-HEATING TIME	Can be manually adjusted by the dip switches on the printed circuit board in the control box.	Micro processor monitors over or under shoot of the mA, and adjusts the pre-heating time automatically.
E.	HIGH VOLTAGE GENERATOR	75 kHz high frequency inverter circuit and Cockcroft circuit.	80 kHz high frequency inverter circuit and Cockcroft circuit.
F.	FILAMENT CIRCUIT	50 kHz high frequency inverter circuit	25 kHz high frequency inverter circuit

(6) –CONTINUED

ELECTRICAL AND RADIATION COMPARISON DATA:

	SIRONA HELIODENT DS (K960819)	PLANMECA PROSTYLE INTRA (K970975)	BELMONT Model 2001CP (K874238)	BELMONT Model 303
A. Focal Point Measurement	0.7mm×0.7mm	0.7mm×0.7mm	0.8mm×0.8mm	0.7mm×0.7mm
B. Rated tube potential	60kV	50,53,55,57,60,63,66,70 kV	60kV, 70kV	60kV, 70kV
C. Rated tube current	7mA	8mA	10mA	4mA, 7mA
D. Maximum rated tube potential	60kV	70kV	70kV	70kV
E. Rated line voltage	100VAC-125VAC	110VAC-115VAC	120VAC	120VAC
F. Line voltage range	90VAC-137.5VAC	99VAC-126VAC	105VAC-130VAC	108VAC-132VAC
G. Range of line voltage regulation	2.5%	10%	2-5%	2-5%
H. Rated line current			14A at 70KV,10mA	10.8A at 70KV,7mA
I. Maximum line current	11A	9.0A	17A at 70KV,10mA	12A at 70KV,7mA
J. Exposure time	0.01-3.2sec., 23steps	0.01-3.2sec., 23steps	0.01-2.0sec. 27steps	0.01-3.2sec., 23steps
K. Timer accuracy	±10%	±10%	±10% or ±10msec., whichever is greater	±5msec. (below 0.1sec. setting) ±10msec. (below 0.1sec. setting & up)
L. Inherent filtration	0.55mmAl Equivalent	1.0mmAl Equivalent at 70kV	1.3mmAl Equivalent	1.7mmAl Equivalent
M. Added filtration			2.0mmAl	0.3mmAl
N. Minimum filtration permanently in useful beam.	2.0mmAl Equivalent	2.0mmAl Equivalent at 70kV	3.3mmAl Equivalent at 70kV	2.0mmAl Equivalent at 70kV
O. Nominal roentgen output 1-Distal end of regular cone 2-Distal end of long cone	1- 10mGy/s±30%		1- 6.3mGy/s±40% (60kV,10mA) 7.8mGy/s±40%(70kV,10mA) 2- 2.2mGy/s±40%(60kV,10mA) 2.9mGy/s±40%(70kV,10mA)	1- 5.4mGy/s±40%(60kV,4mA) 9.4mGy/s±40%(60kV,7mA) 7.1mGy/s±40%(70kV,4mA) 12.4mGy/s±40% (70kV,7mA) 2- 2.4mGy/s±40%(60kV,4mA) 4.2mGy/s±40%(60kV,7mA) 3.1mGy/s±40%(70kV,4mA) 5.5mGy/s±40%(70kV,7mA)
P. Source to skin distance 1-Regular cone 2-Long cone	1-203mm 2-305mm	1-200mm 2-300mm	1-203mm 2-350mm	1-203mm 2-305mm
Q. Leaking technique factor	0.12mA		70kV/0.48mA	70kV/0.14mA
R. Duty cycle	1:60	1:15	1:20	1:50
S. Maximum deviation of tube potential and tube current.	±6.0kV (tube potential) ±0.7mA (tube current)	±2.0kV (tube potential) ±10% (tube current)	±10kV,±5mA (0.01-0.05sec.) ±5kV,±2mA (0.06-2.0sec.)	±10kV,±2mA (below 0.1sec. setting) ±5kV,±1mA (0.1sec. setting & up)
T. Intended Use	All these x-ray systems are AC-powered devices that produce x-rays and are intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.			

11. We plan to start the introduction of this new PHOT-X II, MODEL 303 dental x-ray, as soon as we receive Pre-Market Notification approval from FDA.

If you require any further information, please do not hesitate to contact me at 1-800-223-1192. Ext. 34

Sincerely,

TAKARA BELMONT USA, INC.

Masahiro Kanaya
Vice President

Enclosures:

Attachment A. Initial Report of MODEL 303 x-ray

Attachment B. Software Information

Attachment C. Our Predicated Device BELMONT MODEL 2001CP BROCHURE (K874238)

Attachment D. Competitors Predicated Device SIRONA HELIODENT DS BROCHURE (K960819)

Attachment E. Competitors Predicated Device PLANMECA PROSTYLE INTRA BROCHURE (K960819)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2004

Takara Belmont USA, Inc.
% Ms. Elizabeth Drew
Program Reviewer Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K042260
Trade/Device Name: PHOT-X II, Model 303
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: August 20, 2004
Received: August 23, 2004

Dear Mr. Drew:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K042260

Device Name: PHOT-X II MODEL 303

Indications for Use:

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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042260