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

March 20, 2017

Takara Belmont Corporation, Ltd.
% Dr. Robert Schiff
President
Schiff & Company, Inc.
1120 Bloomfield Avenue, Suite 103
WEST CALDWELL NJ 07006

Re: K163175
Trade/Device Name: Bel-Cypher Pro
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: February 24, 2017
Received: February 24, 2017

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

Robert Ochs, Ph.D.
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)*
K163175

Device Name

Bel-Cypher Pro

Indications for Use *(Describe)*

The Bel-Cypher Pro dental panoramic X-ray system is indicated for use as generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the tooth, jaw, and oral structures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary (as required by 807.92)

(1) SUBMITTER: Takara Belmont Corporation, LTD.
Address: 1-1-2 Chome, Higashi-Shinsaibashi, Chuo-ku
Telephone: 81-6-6213-5945
Contact person: Toshinori Kiyomatsu
Date prepared: October 2016

(2) DEVICE NAME:
Trade Name: Bel-Cypher Pro
Classification Name: Extraoral Source x-ray system
Regulation Number: 872.1800
Product Code: MUH

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

K110160 Bel-Cypher N (Cleared 02/17/2011)
Trade Name: Bel-Cypher N
Common Name: System, X-Ray, Extraoral Source, Digital
Classification Name: Extraoral Source x-ray system
Regulation Number: 872.1800
Product Code: MUH

(4) DESCRIPTION OF THE DEVICE:

The Bel-Cypher Pro is a user-friendly, digital panoramic X-ray system that features bitewing imaging capability, as well as diagnostic panoramic and TMJ imaging capabilities. The Bel-Cypher Pro utilizes a high frequency inverter and has a small focal spot to produce crisp, clear images.

(5) INDICATION FOR USE: The Bel-Cypher Pro dental panoramic X-ray system is indicated for use as generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the tooth, jaw, and oral structures.

(6) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of our new Bel-Cypher Pro and predicate device Bel-Cypher N.

Bel-Cypher Pro (New model)	**Bel-Cypher N (K110160)**
IFU Statement: The Bel-Cypher Pro dental panoramic X-ray system is indicated for use as generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the tooth, jaw, and oral structures.	IFU Statement: The Bel-Cypher N dental panoramic X-ray system is indicated for use as generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the tooth, jaw, and oral structures.

1. COMPARISON TABLE OF SPECIFICATIONSSpecifications	**Takara Belmont Bel-Cypher N**	**Takara Belmont Bel-Cypher Pro**
Focal point measurement	0.5mm x 0.5mm	0.5mm x 0.5mm
Rated peak tube potential	60 kV – 80 kV	60 kV – 80 kV
Rated tube current	2 mA -8 mA	2 mA -8 mA
Maximum rated peak tube potential	80 kV	80 kV
Rated line voltage	120 Vac	120 Vac
Line voltage range	110 Vac – 130 Vac	110 Vac – 130 Vac
Range of line voltage regulation	1 – 3 %	1 – 3 %
Rated line current	11 A at 80 kV – 8 mA	11 A at 80 kV – 8 mA
Maximum line current	11 A at 80 kV – 8 mA	11 A at 80 kV – 8 mA
Exposure time	10 sec at Panoramic mode 2.5sec(×4) at TMJ mode	10 sec at Panoramic mode 10 sec at TMJ (LA) mode 2.5sec(×4) at TMJ mode
Dimension	W:920mm×D:1100mm ×H:2200mm	W:850mm×D:1135mm ×H:2275mm
Weight	130kg	105kg
Timer accuracy	± 5 %+50msec	± 5 %+50msec
Inherent filtration	2.05 mm Al equivalent	3.4 mm Al equivalent
Added filtration	1.5 mmAl	1.5 mmAl
Minimum filtration permanently in useful beam	2.8mmAl (80kV)	2.5mmAl (80 kV)
Nominal roentgen output: panoramic mode	9.34 mGy / 10 sec ±50% (80kv,80mA)	9.34 mGy / 10 sec ±50% (80kv,80mA)
Nominal roentgen output: TMJ mode	9.34 mGy / 10 sec ±50% (80kv,80mA)	9.34 mGy / 10 sec ±50% (80kv,80mA)
Nominal roentgen output: MS mode	N/A	N/A
Nominal roentgen output: Cephalo mode	N/A	N/A
Source to image distance	500 mm	500 mm

Leakage technique factor	0.0014mR/80kV,8mA	0.077mR/80kV,8mA
Duty cycle Panoramic: Bitewing TMJ:	1:60 10 sec exposure with 8 min interval 2.5sec(×4) exposure with 3 min off interval	1:60 10 sec exposure with 8 min interval 4.6 sec exposure with 4.5 min interval 2.5sec(×4) exposure with 2.5 min off interval
Maximum deviation of tube potential	The selected kV ±10 %	The selected kV ± 10 %
Maximum deviation of tube current	The selected mA ± 20 %	The selected mA ± 20 %
Equipment type	Type B equipment	Type B equipment

2. COMPARISON TABLE OF SENSOR SPECIFICATIONS

Specifications	**Takara Belmont Bel-Cypher N**	**Takara Belmont Bel-Cypher Pro**
Mechanical		
Cassette type sensor package: Size	(W) 90mmx (D) 51.2 mmx (H) 174mm	(W) 90mm x (D) 23.7mm x (H)165mm
Cassette type sensor package: Weight	0.5 kg	0.5 kg
Electrical		
Safety and EMC standards Compliance	Safety:IEC60601-1 EMC:CISPR11 Class A	Safety:IEC60601-1 EMC:CISPR11 Class B
Maximum line voltage	DC 5 V	DC 9 V
Environmental		
Operating temperature	0 to 40°C	0 to 40°C
Storage temperature	-10 to 60°C	-10 to 60°C
Humidity	under 93%±3% RH	under 93%±3% RH
Highest permissible temperature limit	60°C	60°C
General		
Acquisition sensor	CMOS sensor	CMOS sensor
Digital processing	Digital	Digital
Computer interface board	Not included with the device	Not included with the device
External connectivity	Giga Ethernet	Giga Ethernet
Acquisition software	Not included with the device	Not included with the device
Enhancement functions	Not included with the device	Not included with the device
Digital storage	Not included with the device	Not included with the device
Hard copy	Not included with the device	Not included with the device
Image sensor active area	148 mm× 6 mm	149.8mm x 6mm
Maximum Flame rate	300f/s	400f/s
Calibration	Automatic	Automatic
System and Component information		
Input electrical ratings	DC 5 V	DC 24 V
Equipment type	Type B equipment	Type B equipment

Fuses	The power supply has the over current protection function and the over voltage protection function	The power supply has the over current protection function and the over voltage protection function
Restricted service statement	Unless otherwise specified, this unit should be serviced only by the manufacturer. It contains no user-serviceable parts.	Unless otherwise specified, this unit should be serviced only by the manufacturer. It contains no user-serviceable parts.
Image characteristics		
Effective pixel size	100μm x 100μm	120μm x 120μm
MTF	49%(@1LP/mm)	52%(@1LP/mm)
DQE	45%(@1LP/mm)	44%(@1LP/mm)
Static resolution (Sensor specifications)	4.5 line pairs per millimeter	4.2 line pairs per millimeter
Noise (rms)	800 electrons	640 electrons
Timing Characteristics		
Timeout after loss of synchronization	N/A	N/A
Timeout when starting acquisition	N/A	N/A

Differences:

There are four minor differences between the Bel-Cypher Pro and the predicate device which is as follows:

1. More sensitive CMOS sensor.
2. Up/Down movement of the unit is motorized for easy operation.
Up/Down movement of Bel-Cypher N was manual.
3. TWAIN software for Bel-Cypher Pro was developed to work with newer operating system (Windows 7, 8 & 10).
We made the sensor driver compatible with windows 10.
Exe files and DLLs of Radiograph software and image reconstruction software were developed under Windows 10 environment.
4. The hosing structure of X-Ray tube was changed to reduce usage of lead.
The housing of predicate device was constructed by soldering brass plates.
The housing of Bel-Cypher Pro uses 6mm stainless steel plates and aluminum plates to make hermetic sealed housing.
We tested and confirmed that new X-Ray housing conforms to IEC60601-1-3 and 21CFR 1020.30(k).

(7) PERFORMANCE STANDARDS APPLIED:

AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

IEC 60601-1-2:2007/(R)2012, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.

IEC 60601-1-3 Edition 2.1 2013-04, Medical Electrical Equipment – Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment.

IEC 60601-2-28 Edition 2.0 2010-03, Medical Electrical Equipment – Part 2-28: Particular Requirements For The Basic Safety And Essential Performance Of X-Ray Tube Assemblies For Medical Diagnosis.

IEC 60601-2-63 Edition 1.0 2012-09, Medical Electrical Equipment – Part 2-63: Particular Requirements For The Basic Safety And Essential Performance Of Dental Extra-Oral X-Ray Equipment.

IEC 60601-2-65 Edition 1.0 2012-09, Medical Electrical Equipment – Part 2-65: Particular Requirements For The Basic Safety And Essential Performance Of Dental Intra-Oral-X-Ray Equipment.

IEC 61223-3-4 First Edition 2000-03, Evaluation And Routine Testing In Medical Imaging Departments - Part 3-4: Acceptance Tests - Imaging Performance Of Dental X-Ray.

ISO 14971 Second Edition 2007-03-01, Medical Devices - Application Of Risk Management To Medical Devices.

(8) CONCLUSION: The Bel-Cypher Pro has the same intended use and technology characteristics as the predicate device Bel-Cypher N.

Modifications of software were tested and confirmed based on applicable standards. We also tested all of the radiograph modes and conmfirmed images are equvalent to the ones taken by thpredicate device.

X-Ray tube housing was tested and confirmed that new X-Ray housing conforms to IEC60601-1-3 and 21CFR 1020.30(k).

The proposed device is substantially equivalent to the noted predicate and is safe and effective for its intended use.