



Food and Drug Administration
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June 20, 2016

Radiotecnologia Industrial S.A. De C.V.
% Claude Berthoin, President
Denterprise International, Inc./ 510k FDA Consulting
100 East Granada Blvd
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Ormond Beach, FL 32176

Re: K160458
Trade/Device Name: BI IMAGE-X EVOLUTION
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: May 6, 2016
Received: May 10, 2016

Dear Claude Berthoin:

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,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160458

Device Name

BI IMAGE-X EVOLUTION

Indications for Use (Describe)

The BI IMAGE-X EVOLUTION device is an X-Ray generator designed for radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure in combination with an intraoral 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k FDA Consulting

Medical Device Clearance

100 East Granada Blvd., Suite 219

Ormond Beach, FL 32176

386-506-8711

510(k) Summary

Submitter/Applicant

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Device Classification

Trade Name: BI IMAGE-X EVOLUTION
Common Name: Extraoral Source X-ray System
Classification Name: Unit, X-Ray, Extraoral with Timer
Regulation Number: 21 CFR 872.1800
Product Code: EHD
Regulatory Class: 2
510k Review Panel: Dental

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K122582
Date Cleared	December 7, 2012
Trade Name:	Dental X-Ray Z70
Common Name:	Extraoral Source X-ray System
Classification Name:	Unit, X-Ray, Extraoral with Timer
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Regulatory Class:	2
510k Review Panel:	Dental

Indication for Use

The BI IMAGE-X EVOLUTION is an extraoral x-ray generator system is designed to be used by dental professionals for radiographic examinations to assist with diagnosis of diseases of the teeth, jaw, and oral structure in combination with an intraoral image receptor.

Intended Use

The BI IMAGE -X EVOLUTION device is an extroral x-ray generator that provides the radiation necessary for the formation of a radiographic image from which a radiographic diagnosis may be made.

Device Description

The device is designed to be used by dental professionals for radiographic examinations to assist with diagnosis of diseases of the teeth, jaw, and oral structure by exposing an x-ray image receptor to ionizing radiation. The x-ray source, a tube, is located outside the mouth. All three conventional types of intraoral receptors can be used with this device: analog x-ray film, digital phosphorous plates, and digital x-ray sensors. The Bi Image-X Evolution is a wall mounted device or can also be a floor model on a stand. Choice of model is a matter of functional utility in the dental operatory and personal preference by the medical professional. The type of model used does not change the performance of the device.

Different models neither affect the device's indications for use nor raise differing issues of safety or effectiveness.

Comparison of Technological data on next page

Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Table 5 -- Technological Comparison

	Subject Device	Predicate Device K122582
Device	BI IMAGE-X	Dental X-Ray Z70
510(k) Owner	Radiotecnologia Industrial S.A. de C.V. (Mexico)	XZeal Technologies, Inc. (Kissimmee, FL)
Classification & Product Code	872.72.1800; EHD	872.1800; EHD
Device Description	Extroral x-ray system used for dental radiographic examinations and diagnosing.	Extroral x-ray system used for dental radiographic examinations and diagnosing.
Common Name	Extraoral Source X-ray System	Extraoral Source X-ray System
Models	Wall Mount, Mobile and Column Units	Wall Mount, Mobile and Column Units
Indication for Use	The BI IMAGE-X EVOLUTION is an extraoral x-ray generator system is designed to be used by dental professionals for radiographic examinations to assist with diagnosis of diseases of the teeth, jaw, and oral structure in combination with an intraoral image receptor.	The Dental X-ray Z70 device is an X-Ray generator that provides the radiation necessary for the formation of a radiographic image from which a radiographic diagnosis may be made.
Intended Use	The BI IMAGE -X EVOLUTION device is an extraoral x-ray generator that provides the radiation necessary for the formation of a radiographic image from which a	Extraoral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth.

	radiographic diagnosis may be made.	
Electric Power Voltage	108-132 VAC Monophase rectified	120 VAC ± 10% or 230 VAC ± 10%
Rated Current	10A max (120V)	9 A (120V) – 4A (230V)
Type of Power Supply	50/60 Hz	50/60 Hz
kVp (kilovolt peak)	70 kVp +/- 15% with 108-132 V	70 kVp ± 10%
Exposure Time	0.01-2.2 sec	0.06 – 2.50 sec
Current to Tube	10 mA +/- 20%	7 mA ± 1.40
Maximum Radiation Field	Ø 60 mm	Ø 60 mm
Focal Point	0.8mm (IEC366)	0.8 mm x 0.8 mm (IEC 336)
X-Ray Generator	AC – Alternate Current	AC – Alternate Current
Operator Exposure Control	Deadman Switch	Deadman Switch
Exposure Interval (Duty Cycle)	1:32	1:60
Minimum Distance between the source and the skin - SSD	20 cm	20 cm
Fuses	10A 250V	10A 230V
Operating Temperature Range	-20°C- + 70°C	-20°C - + 55°C
Fixed Arm	27.56 inches (70 cm)	27.56 inches (70 cm)
Standards of Conformity	IEC 60601-1 IEC 60601-6 IEC 60601-3 IEC 60601-2-28 EN 60601-1-2	EN 60601-1 EN 60601-2-28 EN 60601-2-54 EN 60601-1-3 EN 60601-1-2

The above comparison shows the subject and predicate devices have substantially similar technology characteristics.

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

EMC and Electrical Safety – IEC 60601-1 3rd Edition (which include IEC test specifications: 60601-1-6, 60601-1-3, 60601-2-28) and EN 650601-1-2. The testing data reports for the subject device are provided in this petition. Tests were conducted by independent laboratory (Met Laboratories, Inc. 33439 Western Avenue, Union city, CA 94587).

This device conforms to all applicable performance standards in 21CFR 1020.030 and 1020.31.

Software – Software verification and validation testing and risk analysis assessment were performed by Radiotech and is a part of this submission.

Risk Analysis Information

Risk analysis includes particular recommendations to address radiation exposure to the user under mobile operating conditions. Operators should always read the user manuals for medical devices and take the necessary precautions before using the device. Methods to reduce exposure is recommended safety precautions such as wearing personnel monitoring and protective equipment.

Conclusion

The subject and the predicate device have the same intended use and the same technological features. The BI IMAGE – X and the Dental X-Ray Z70 share the same principles of operation and use similar imaging firmware. The conclusion is that the subject device is as safe and effective as the predicate.

The BI IMAGE – X warrants a finding of substantial equivalence to the legally marketed Dental X-Ray Z70 and thus clearance for premarket activities in the United States.