K110160
FEB 17 2011

510(k) SUMMARY

Schiff & Company, located in West Caldwell, NJ and on behalf of Takara Belmont, USA, Inc., is submitting this Special 510(k) Premarket Notification for Bel-Cypher N. The Bel-Cypher N dental panoramic X-ray system is indicated for use as a generator of radiographic images of the dento-maxilofacial region and is intended for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Device Details:

Device Class:	CFR 872.1800 identifies the device as an Extraoral source x-ray system, Class II
Trade or Proprietary Name:	Bel-Cypher N
Common or Usual Name:	System, X-ray, Extraoral source, digital
Classification Name:	Extraoral source x-ray system
Performance Standards:	IEC 60601-1 (1995), IEC 60601-1-1 (2000), IEC 60601-1-2 (2004), IEC 60601-1-3 (1994), IEC 60601-1-4 (1999), IEC 60601-2-7 (1998), IEC60601-2-28 (1993), IEC60601-2-32 (1994)
Labeling:	Copies are included with this submission.

Establishment Details:

Establishment Registration No: 96114485

Takara Belmont USA, Inc.
Belmont Equipment Division
101 Belmont Drive
Somerset, NJ 08873-1204

Performance Compliance:

IEC 60601-1 (1995), IEC 60601-1-1 (2000), IEC 60601-1-2 (2004), IEC 60601-1-3 (1994), IEC 60601-1-4 (1999), IEC 60601-2-7 (1998), IEC60601-2-28 (1993), IEC60601-2-32 (1994)

Substantially Equivalent:

The Bel-Cypher is substantially equivalent to:

DEVICE NAME	510(K) NUMBER	MANUFACTURER
Bel-Cypher	090020	Takara Belmont

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Takara Belmont Corporation
% Mr. Kunihiko Sobue
Product Manager
Takara Belmont USA, Inc.
101 Belmont DR
SOMERSET NJ 08873

FEB 17 2011

Re: K110160
Trade/Device Name: Bel-Cypher N
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: January 18, 2011
Received: January 19, 2011

Dear Mr. Sobue:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110160

Device Name: Bel-Cypher N

Indication for Use:

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.

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

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

Concurrence of CDRH, Offic of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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