DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 22, 2016

Takara Belmont Corporation
c/o Dr. Robert Schiff
President
1120 Bloomfield Avenue, Suite 103
West Caldwell, New Jersey 07006

Re: K152100
Trade/Device Name: Evogue Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: December 11, 2015
Received: December 15, 2015

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" (21CFR 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
To be assigned K152100

Device Name
BELMONT, Evogue Dental Unit series

Indications for Use *(Describe)*
Evogue Dental Unit series are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dental operatory.

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) PREMARKET NOTIFICATION FOR EVOGUE DENTAL UNIT
TAKARA BELMONT CORPORATION, LTD.

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: July 2015

(2) DEVICE NAME: Unit, Operative Dental
Trade Name: Evogue Dental Unit
Common Name: Dental Unit
Classification Name: Unit, Operative Dental
Regulation Number: 872.6640

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

K000799 Belmont Unit, Model 2000 Series (Approved 05/17/2000)

(4) DESCRIPTION OF THE DEVICE: This product is an active therapeutic device intended to administer or exchange energy of electric, air and water for the exclusive use for diagnoses, treatments and relative procedures of dentistry, and its characteristic is not in a potentially hazardous way between such energy and human body, taking account of the nature, the density and site of application of the energy.

The product must be operated or handled by the qualified dentists or by dental staffs under the supervision of the dentist.

Such dentists or dental staffs should instruct and/or assist the patients to approach to and leave from the product.

Patients should not be allowed to operate or handle the product unless he/she is so instructed.

The air unit system uses compressed air to drive air turbine, air motor and air scaler. The new Evogue Dental Unit is air unit system. The function and components used for Evogue Dental Unit are very similar to X-Calibur unit (Belmont Model 2000 Series, K000799). Though the Evogue Dental Unit is typical air system, it does have upgrade ability to use micro motor with external touch pad (MX2 Optima) and integrated type electric scaler (Cavitron).

The foot control regulates drive air to the active handpiece to control the rotation speed of turbine and air motor. Also controls the frequency of air scaler.

It provides an air signal that activates air coolant and water coolant flow. The foot control is equipped with a wet/dry toggle to turn the water coolant on or off.

(5) INTENDED USE: Evogue Dental Unit series are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dental operatory.

(6) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of our new Evogue Dental Unit and predicate device Belmont Unit, Model 2000 Series.

Evogue Dental Unit (New model)	**Belmont Model 2000 Series Dental Unit & Accessories (X-Calibur Unit)**
Applying	K000799
Chair, Cabinet Mounting	Chair, Cabinet & Cart Mounting
IFU Statement: Evogue Dental Unit series are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dental operatory.***	IFU Statement: Evogue Dental Unit series are intended for the Dentists, Hygienists, and Dental assistants for traditional and normal patient treatment procedures in the dental operatory. The design function, and positioning of the unit and accessories are similar to most all other dental units manufactured for this specific purpose over the past twenty years
***PLEASE NOTE that the IFU's are similar in how they are used for traditional patient dental treatment; however, the IFU's for the predicate device provides a more descriptive comparison to other traditional dental units. This detail does not affect the intended use of the device.	
Autoclavbable H.V.E. & Saliva Ejectors are standard	Autoclavbable H.V.E. & Saliva Ejectors are standard
Foot Control is standard	Foot Control is standard
Utility Box with manual air & water shut-off valves, pilot operated shut-off valves, regulators, gages, and air & water filters	Utility Box with manual air & water shut-off valves, pilot operated shut-off valves, regulators, gages, and air & water filters
Three cutting handpieces and automatic controls are standard, up to five handpieces are optional	Three cutting handpieces and automatic controls are standard, up to four handpieces are optional
Non-retracting water system for handpieces and syringes standard	Non-retracting water system for handpieces and syringes standard
3-way syringe with quick disconnect tip and autoclavable tips standard. Asepsis tubing standard	3-way syringe with quick disconnect tip and autoclavable tips standard. Asepsis tubing standard
Aseptic baggable type instrument holders standard	Aseptic baggable type instrument holders standard
Cuspidor with cup filler is standard. Gravity drain	Cuspidor with cup filler is standard. Gravity drain
H.V.E. & Saliva ejector asepsis tubing with autoclavable instrument holders, standard with brake-away safety feature	H.V.E. & Saliva ejector asepsis tubing with autoclavable instrument holders, standard with brake-away safety feature

(7) PERFORMANCE STANDARDS APPLIED:

IEC 60601-1-2, IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

ISO 7405 (Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, Second Edition 12/15/08),

ISO 7405:2008 specifies test methods for the evaluation of biological effects of medical devices used in dentistry. It includes testing of pharmacological agents that are an integral part of the device under test.

ISO 7405:2008 does not cover testing of materials and devices that do not come into direct or indirect contact with the patient's body.

ISO 7494-1 (Dentistry - Dental units - Part 1: General requirements and test methods, Second Edition 8/15/11)

This part of ISO 7494 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered.

It also specifies requirements for the manufacturer’s instructions, marking and packaging.

ISO 7494-2 (Dentistry - Dental units - Part 2: Water and air supply, First Edition 03/01/2003)

This part of ISO 7494 specifies requirements and test methods for materials, design and construction of the water and air supply within dental units in order to ensure that compressed water and air supplied via the dental unit are of appropriate quality. It includes provisions for the prevention of retraction of oral fluids into the water supply f the dental unit.

This part of ISO 7494 does not address prevention of contamination and/or proliferation of hazardous micro-organisms (for example bacteria, viruses) in the dental unit.

ISO 9168 (Dentistry - Hose connectors for air driven dental handpieces, Third Version 07/15/2009)

ISO 9168:2009 is applicable for achieving reliable interchangeability between hoses from dental units and dental handpieces.

ISO 9168:2009 specifies four types of hose connector for use between air driven dental handpieces and the flexible hoses of the dental unit which supply the handpieces with water, air and light, and provide for exhaust.

ISO 14457 (Dentistry - Handpieces and motors, First Edition 09/15/2012)

ISO 14457:2012 is applicable to handpieces and motors used in dentistry for patient contact, regardless of their construction. It specifies requirements, test methods, manufacturer's information, marking and packaging.

ISO 14457:2012 is applicable to:

1. straight and geared angle handpieces, including handpiece attachments;

2. high-speed air turbine handpieces;

3. air motors

4. electrical motors

5. prophy handpieces

(8) CONCLUSION: The Evogue Dental Unit has the same intended use and technology characteristics as the predicate device Belmont Unit, Model 2000 Series. The proposed device is substantially equivalent to the noted predicate.