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

August 14, 2015

Union Dental S.A.
José Luis Rodriguez Blanco
Technical Director
Paseo de la Estación, 4,
28550 Tielmes, Madrid
SPAIN

Re: K150432
Trade/Device Name: IDODENTINE Dental Polymer Blank
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG, EBI, MQC
Dated: April 30, 2015
Received: May 20, 2015

Dear Mr. Rodriguez Blanco:

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 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150432

Device Name
IDODENTINE (DENTAL POLYMER BLANK)

Indications for Use *(Describe)*
Acrylic polymer blank particularly suitable for making removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM.
Indications:
- Temporary anterior and posterior crowns
- Temporary anterior and posterior bridges with up to two adjacent pontics
- Implant supported temporary restorations
Maximum recommended usage period: 12 months
- Removable structures for dentures (dental bases)
- Removable structures for therapeutic restorations (bite splints or occlusal splints)

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.

To: DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Premarket Notification Submission (510(k)): K150432

Dental polymer blanks

5. 510(K) SUMMARY

Date of Summary: April 30th 2015

1- Submitter

Company name: **Union Dental S.A**
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2- Device Name

Proprietary name: **IDODENTINE** blanks

Common name: **Dental polymer blanks** (discs or blocks)

3- Common or usual name and classification

Classification name: Temporary crown and bridge resin
Regulation number: 872.3770
Product code: **EBG**, EBI, MQC
Classification. Class II.

4- Predicate Device information

Predicate Device selected to demonstrate substantial equivalence

Company	Predicate Device	Intended use	510K nr
MERZ Dental GmbH	**M-PM-DISC (Tooth colored)**	**Temporary crown and bridges**	**K071548**

Reference predicates

Company	**Predicate Device**	**510K nr**
MERZ Dental GmbH	M-PM-DISC (Clear)	**K134015**
MERZ Dental GmbH	M-PM-DISC (Pink)	**K140758**
MERZ Dental GmbH	ART BLOCK Temp	**K080556**

5- Devices description

Dental polymer blank is a circular solid (disc) or rectangular solid (block) of PMMA with or without post attachment for use in a Cad-controlled milling machine for production of provisional restorative prostheses such as dental crowns and bridges and removable dental structures. These blanks are available in a variety of shapes for different milling systems and are also available in variety of dental shades.

Dental polymer blanks are made with the same material (Hot cured PMMA) that is used for the manufacture of the Union Dental artificial teeth brands ODILUX and ODIPAL (K070591). These polymer discs or blocks are especially suited for creating dental structures by means of milling CAD/CAM techniques commonly used in the dental laboratories and in dental practice. The elaboration is designed by a professional, a dental technician or a dentist. This guarantees their correct use, since it is an intermediate product in order to manufacture a custom-made product.

6- Intended use

Acrylic polymer blank particularly suitable for making removable or temporary dental structures such as crowns and bridges using milling technology using CAD/CAM.

Indications:

- ***Temporary anterior and posterior crowns***
- ***Temporary anterior and posterior bridges with up to two adjacent pontics***
- ***Implant supported temporary restorations***
  Maximum recommended usage period: 12 months
- ***Removable structures for dentures (dental bases)***
- ***Removable structures for therapeutic restorations (bite splints or occlusal splints)***

7- Technological characteristic and substantial equivalence

Chemical Composition:
The device has similar chemical composition as the predicate device. ***(Polymethylmetacrilate, commonly named as PMMA***, the same PMMA that is used for produce acrylic teeth***)***

Technological characteristics:
The device has the same technological characteristics as the predicate device (Hot cured PMMA). And the device is similar in sizes, shapes and color scale as the above predicate devices. **(Variable thickness milling blank (Disc or block) in Vita colours (A1, A2…), or pink or clear)**

Properties:
The device has comparable physical and chemical properties as the predicate device. ***(Meeting the requirements of ISO standards for the polymer-based dental materials, ISO 10477, 20795, 22112)***

Usage:
The device has similar indications for use as the sum of the predicate devices: ***Milling blank in the fabrication of temporary restorative dental prostheses such as dental crowns and bridges*** M-PM-DISC (Tooth colored) ***or removable dental structures like denture bases*** M-PM-DISC (Pink) ***and bite splints*** M-PM-DISC (Clear)***.***

8- Materials

Polymers based on PMMA are well established products; these products have been used as an established part of dental prosthesis techniques for over 70 years. UNION DENTAL S.A. has been manufactured this type of polymers since its foundation in 1965.

Dental polymer blanks (the subject device and predicate devices) are made with the same (powder / liquid) mix that is used for the manufacture of artificial teeth (Hot cured PMMA) and all the components of these products had been suitably considered and evaluated in the bibliography. PMMA is biocompatible for this intended use.

9- Preclinical testing and standards

Clinical and Non clinical performance

Idodentine dental polymer blank has not been tested clinically. Both Idodentine and predicate devices are fabricated from the same PMMA that is used for produce acrylic teeth. This PMMA has been tested for biocompatibility and physical properties *(see the biocompatibility and non –clinical testing section).*

This PMMA used has been rated as biocompatible and Non toxic and this PMMA material also met the applicable requirements of ISO 10447(crown & bridges material), ISO 20795(removable dentures) and ISO 22112(polymer teeth) standards.

The subject device has passed testing according to **ISO 10477/2004: DENTISTRY – POLYMER-BASED CROWN AND BRIDGE MATERIALS.** This international standard specifies the classification, requirements and test methods for the polymer-based crown and bridge materials. The subject device also has passed testing according to **ISO 10993-5 and has been rated as Non cytotoxic**

Comparison table:

Physical parameters	Biocompatibility	Flexural strength	Water absorption:	Water solubility:	Residual monomer content:
ISO 10477 ISO 20795 requirements	ISO 10993	$\geq$ 50 MPa $\geq$ 65 MPa	$\leq$ 0.040 mg/mm^3 $\leq$ 0.032 mg/mm^3	$\leq$ 0.007.5 mg/mm^3 $\leq$ 0.001.6 mg/mm^3	$\leq$ 2,2%
PREDICATE (data from technical documentation of the manufacturer)	ISO 10993-5 Non cytotoxic	91.5	0.026 mg/mm^3	0.0002 mg/mm^3	1%
IDODENTINE	ISO10993--5 Non cytotoxic (NIOM test report 025/10)	**90 MPa** (NIOM test report 026/10)	**0.023 mg/mm^3**, (NIOM test report 026/10)	**0.0000 mg/mm^3** (NIOM test report 026/10)	**1,4%** (Innovatech GC/MS test 115201-A)

Discussion of the nonclinical test submitted:

Both **subject device** and predicate device meet the requirements of applicable ISO standards and the results of the non-clinical testing are so similar between the device and the predicate that, taking account the error percentages of the measures and possible differences in test method(as is the case of monomer content where ISO 20795 standard allows to use different ways to calculate the final result(GC, HPLC...), we can speak about predicate and device have similar results in the non clinical testing.

The tests discussed above indicate that the subject device is substantially equivalent in to the predicate device.

10-Conclusions

The new and predicate devices are similar in function, and similar in composition, production technology and intended use. **This supports that the applicant device is substantially equivalent to the predicate device.**