DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 15, 2016

Dental Solutions, LLC
℅ Brian Edwards
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Namsa
4050 Olson Memorial Highway
Golden Valley, Minnesota 55442

Re: K160498
Trade/Device Name: Dentivera Milling Disc
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: February 22, 2016
Received: May 5, 2016

Dear Brian Edwards:

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,

Susan Runner DDS, MA

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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)*
K160498

Device Name

Dentivera™ Milling Disc

Indications for Use *(Describe)*

The Dentivera™ Milling Disc is a thermoplastic denture base resin designed for the manufacture of full and partial removable dentures and overdentures.

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.

1.0 510(k) Summary – K160498

1.1 Submission Sponsor

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1.2 Submission Correspondent

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1.3 Date Prepared

June 8, 2016

1.4 Device Identification

Trade/Proprietary Name:	Dentivera™ Milling Disc
Common/Usual Name:	Denture Base Resin
Classification Name:	Denture Relining, Repairing, and Rebasing Resin
Classification Regulation:	21 CFR Part 872.3760
Product Code:	EBI
Device Class:	II
Classification Panel:	Dental Devices
Model Numbers:	TBD

1.5 Predicate Devices

The predicate device for the Dentivera™ Milling Disc is the Paladon 65 denture relining, repairing, and rebasing resin cleared on June 22, 1990 under 510(k) Number K901789.

Both resin products are indicated for the manufacture of full and partial removable dentures and implant overdentures.

1.6 Device Description

The Dentivera™ Milling Discs are cylindrical, puck-shaped discs made from Ultaire™ AKP, an arylketone thermoplastic polymer resin with zinc oxide (ZnO) as an additive stabilizer.

Dentivera™ Milling Disc

The milling discs are machined into partial or full removable denture frames using available dental CAD/CAM systems. The nominal dimensions are 98 mm in diameter and 28 mm thick. This is the size that would fit most of the commercial dental milling machines currently used in dental laboratories.

1.7 Indication for Use

The Dentivera™ Milling Disc is a thermoplastic denture base resin designed for the manufacture of full and partial removable dentures and overdentures.

1.8 Contraindications

The Dentivera™ Milling Disc is not to be used in full removable dentures or permanent (i.e., cemented or implant retained) crowns, caps, bridges or superstructures.

1.9 Comparison to Predicates

The Dentivera™ Milling Disc resin is substantially equivalent to the Paladon 65 denture base resin in its performance and strength for the use in the manufacture of full and partial removable dentures and overdentures. The Paladon 65 denture based resin was cleared under 510(k) Number K901789. Both products are denture base materials used in the manufacture of full and partial removable dentures.

When the Dentivera™ Milling Disc and the Paladon 65 are formed into the final denture base and frame products, both materials are used in identical ways and are both compliant with ISO 20795-1 for the strength and durability of denture base materials.

Table 3: Dental Solutions Dentivera™ Milling Disc Substantial Equivalence Table

	Predicate Device (Predicate Device)	**Dental Solutions Milling Disc (Subject Device)**	**Discussion**
510(k) Number	K901789	K160498	N/A
Manufacturer	Heraeus Kulzer, LLC 300 Heraeus Way South Bend, Indiana 46614	Dental Solutions, LLC. P.O. Box 270725 7701 Golden Valley Rd. Golden Valley, MN 55427	N/A
Classification	II	II	Same
Product Code	EBI	EBI	Same
Regulation	21 CFR 872.3760	21 CFR 872.3760	Same
Indications for Use	Paladon 65 is a denture base resin designed for fixed and removable dentures: Full and partial dentures.	The Dentivera™ Milling Disc is a thermoplastic denture base resin designed for the manufacture of full and partial removable dentures and overdentures.	Substantially Equivalent
Main Chemical Composition	Polymethyl acrylate; methyl methacrylate, dimethyl acrylate, impact modifier	Arylketone thermoplastic resin	Substantially Equivalent
Shelf Life	5 years	10 years	Substantially Equivalent
Denture Fabrication Method	Mixing and molding of resin into physical mold followed by curing of resin	Pre-molding of resin into rigid disc followed by CAD/CAM milling of denture	Substantially Equivalent
Flexural Strength > 65 MPa (ISO 20795-1)	Pass	Pass	Substantially Equivalent
Flexural Modulus > 2000 MPa (ISO 20795-1)	Pass	Pass	Substantially Equivalent
Water Sorption ⩽ 32 µg/mm^3 (ISO 20795-1)	Pass	Pass	Substantially Equivalent
Water Solubility ⩽ 1.6 µg/mm^3 (ISO 20795-1)	Pass	Pass	Substantially Equivalent

As outlined above, the Dental Solutions Denitvera™ Milling Disc resin and the Paladon 65 resin are substantially equivalent is use and both materials physical properties exceed the minimum requirements of ISO 20795-1 for Denture base polymers and resins. The use of the Dentivera™ Milling Disc does not result in any additional risks over and above that of the Paladon 65.

1.10 Performance Testing

Side-by-side testing of the Dentivera™ Milling Disc resin and the Paladon 65 resins showed that both materials are compliant with the *ISO 20795-1: Dentistry - Base polymers Part 1: Denture base polymers* standard relating to mechanical properties of denture base materials. These results are summarized in the Substantial Equivalence table above.

In addition, biocompatibility testing was performed on the Dentivera™ Milling Disc resin in accordance with ISO 10993-1.

Table 4: Biocompatibility Testing Summary of Dentivera™ Milling Disc Ultaire™ AKP resin

Test	Standard Applied	Relevant Results
Cytotoxicity MEM Elution Method	ISO 10993-5	Non-cytotoxic
Sensitization Guinea Pig Maximization	ISO 10993-10	Non-sensitizing
Intracutaneous Reactivity	ISO 10993-10	Non-irritating
Systemic Toxicity Acute Systemic Injection	ISO 10993-11	Non-toxic
13 Week Subchronic Systemic Toxicity in Rats, Subcutaneous Implantation	ISO 10993-6	Non-toxic
Intramuscular Implantation Study - 4 Week	ISO 10993-6	Non-irritating
Bacterial Reverse Mutation Assay	ISO 10993-3	Non-mutagenic
Genotoxicity: Mouse Peripheral Blood Micronucleus Study	ISO 10993-3	Non-genotoxic
Genotoxicity: Mouse Lymphoma Assay	ISO 10993-3	Non-genotoxic
Pyrogen Test	USP <151>	Non-pyrogenic

Test	Standard Applied	Relevant Results
Chemical Characterization of PXM-15263 Resin	ISO 10993-18	Pass
Chemical Characterization of PXM-15263 Discs	ISO 10993-18	Pass
Biological Risk Assessment Dental Milling Disc	ISO 10993-1 ISO 14071	Pass

1.11 Conclusion

Dental Solutions LLC considers the Dentivera™ Milling Disc denture base resin to be substantially equivalent to the Paladon 65 denture base resin in that its use and performance as a denture base resin is equivalent to the predicate in terms of chemical characterization, biocompatibility and ISO based performance testing. . This conclusion is based upon the devices' similarities in intended use, design, and mechanical properties.