DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 21, 2015

Dentca, Inc.
c/o Mr. Claude Berthoin
Denterprise International, Inc.
110 East Granada Blvd, Suite 207
Ormond Beach, Florida 32176

Re: K143033
Trade/Device Name: Dentca Denture Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: June 15, 2015
Received: June 18, 2015

Dear Mr. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143033

Device Name

Dentca Denture Base

Indications for Use *(Describe)*

Dentca Denture Base is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-cured and auto polymerizing resins.

Fabrication of dental prosthetics with Dentca Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.

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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K143033

510(k) Summary

Submitter

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Contact Person: Jason Lee
Date Prepared: July 20, 2015

Consultant

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Contact Person: Claude Berthoin, President

Device Classification

Trade Name:	Dentca Denture Base
Common Name:	Dental Acrylic Resin
Regulation Number:	21 CFR 872.3760
Regulation Name:	Denture relining, repairing, or rebasing resin
Product Code:	EBI
Submission Type:	510(k)
Regulatory Class:	2
Medical Specialty:	Dental

Primary Predicate Device

The following primary predicate is a legally marketed, post-amendment device:

510(k) Number:	K032892
Clearance Date:	September 26, 2003
510(k) Trade Name:	Trubyte Denture Base Resin System
Actual trade names:	Trubyte Triad VLC (Visible Light Cure) Denture Base System; Trubyte Eclipse VLC Denture Base System
Manufacturer:	Dentsply International, Inc. (York, PA, USA)
Regulation & PC:	872.3760; EBI

Reference Device

The following reference predicate is a legally marketed, post-amendment device:

510(k) Number:	K102776
Clearance Date:	February 18, 2011
510(k) Trade Name:	e-Dent Temporary Resin and Extraoral Curing System
Actual Trade Name:	EnvisionTEC E-Dent 100
Manufacturer:	DentaMed GmbH (Friedberg, Germany)
Regulation & PC:	872.3770; EBG

Device Description

Dentca Denture Base is a photosensitive resin intended to fabricate removable dentures in a CAD/CAM additive printing process.

The Dentca polymer is a viscous solution of the following compounds: methacrylate-based resins, a photoinitiator that activates at 405 nm visible (blue) light, an inhibitor, and pigments. It comes in two sizes, large and small bottles (see photo at right). It is a Type 4 (light-activated) acrylic resin as classified by ANSI/ADA Specification No. 12.

The denture fabrication process begins with a traditional casting impression of the oral region in the dentist office. This impression is sent to a dental lab for conversion to digital image in an optical impression system. The denture base is then made layer-by-layer in a stereolithographic laser printer. After attachment of preformed plastic teeth, the denture is cured in a light chamber, and, lastly, sent back to the dentist for try-in and final adjustment.

Key performance specifications include:

Flexural strength…	90.2 MPa
Flexural modulus…	2,290 MPa
Residual monomer…	Not detectable
Water sorption…	14 ug/mm3
Water solubility…	1.3 ug/mm3

Indications For Use

Dentca Denture Base is a light-cured resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-cured and auto polymerizing resins.

Fabrication of dental prosthetics with Dentca Denture Base requires a computer-aided design and manufacturing (CAD/CAM) system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereolithographic additive printer, and curing light equipment.

Both the subject and predicate are light-cure resins indicated for fabrication and repair of removable dental prostheses.

Comparison Of Technological Characteristics With Predicate

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

Table 5 -- Comparison Of Technical Features

	K143033 Subject Device	K032892 Predicate Device	Differences
Device Names	**Dentca Denture Base**	**Dentsply Trubyte Denture Base Resin System**	**NA**
Classification & Product Code	872.3760; EBI	872.3760; EBI	SAME CLASSIFICATION
Intended Use	Fabrication and repair of removable dentures, appliances and prostheses	Fabrication and repair of removable dentures, appliances and prostheses	SAME INTENDED USE
Indication For Use	Dentca Denture Base is a light-cure resin indicated for fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional heat-cured and auto polymerizing resins... The device requires a CAD/CAM system that includes the following components not part of the device: oral casting impression, digital denture base file created in an optical impression system, stereo lithographic additive printer, and curing light equipment.	Trubyte Denture Base Resin System is [a light-cure resin] indicated for fabrication and repair of dentures, appliances and prostheses, and for relining of denture surfaces.	BOTH DEVICES ARE LIGHT-CURE RESINS INDICATED FOR FABRICATION AND REPAIR OF REMOVABLE DENTAL PROSTHESES.
Device Description			
Acrylic Resin	Light-cure resin	Light-cure resin	SAME TECHNOLGOY
Chemical Characterization	Methacrylate-based resins with photoinitiator, inhibitor and pigments	Methacrylate-based resins with photoinitiator, inhibitor and pigments	SAME TECHNOLGOY
Polymerization (Curing) Method	Visible light	Visible light	SAME TECHNOLGOY
Product State	Pre-mixed resin	Pre-mixed resin	SAME TECHNOLGOY
Fabrication of Denture Base	Automated 3D printing of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber	Manual application of resin in multiple layers, each light-cured before adding next layer, with post curing in light chamber	Manual vs. automated application technology
Post Curing	Visible light-curing unit	Visible light-curing unit	SAME TECHNOLGOY
Teeth Assemble	Bonding	Bonding	SAME TECHNOLGOY

The above comparison shows the only technological difference between the denture polymers is method of resin application to fabricate the denture base, with the subject applied in an automated optical method and the predicate in a manual mechanical process.

A comparison of the subject and reference showed that both devices fabricate the denture base in the same manner, via automated application of a light-cure resin in an additive CAD/CAM printer.

Performance Data

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

Biocompatibility Testing

The biocompatibility evaluation for Dentca Denture Base was conducted in accordance with the FDA Blue Book Memorandum #G95-1 and International Standard ISO 10993-1, as recognized by FDA. The battery of testing included the following tests:

- Genotoxicity
- Cytotoxicity
- Sensitization
- Irritation
- Acute Toxicity
- Material Characterization

The denture base is considered tissue contacting for a period longer than 30 days (a removable prosthesis).

Electrical Safety and EMC

The low voltage 3D printer used to fabricate the denture base from the Dentca Denture Base light-cure resin was certified by the printer manufacturer to conform to EN 60950 (Safety of Information Technology Equipment) and the following EMC standards: EN 55022, EN 55024, EN 61000-3-2, EN 61000-3-3, and EN 60825-1.

Software Verification and Validation Testing

The optical scanning impression system used to convert cast impressions into 3D digital images was validated by the scanner manufacturer in conformance with ISO 12836.

Bench Testing

Dentca Denture Base was tested for conformity with the industry consensus standard ISO 20795-1.

Conclusions

The subject and predicate devices have the same intended use and substantially similar technological characteristics, with the exception of the method of fabricating the denture base. Because the subject introduces a new additive printing technology as part of a CAD/CAM manufacturing process, an acceptable reference device was brought in to demonstrate prior use of this new technology.

The non-clinical data support the substantial equivalence of the subject device and demonstrate that Dentca Denture Base should perform as intended in the specified use conditions.