Park Dental Research Corporation
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030

October 12, 2018

Re: K181220
Trade/Device Name: Juell 3D Volo Base
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: July 3, 2018
Received: July 16, 2018

Dear Angela Blackwell:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

For Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181220

Device Name
Juell 3D Volo Base

Indications for Use *(Describe)*
Juell 3D Volo Base is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. Juell 3D Volo Base is intended exclusively for professional dental work. Fabrication of denture bases with Juell 3D Volo Base requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit.

Juell 3D Volo Base is compatible with the following CAD/CAM systems components:

Design

	Brand	Type
Scanner	Dental Wings	I series
Design Software	Dental Wings	DWOS

Printing

	Brand	Type	Software
Printer	Juell 3D	DLP	Flash OC

Post-Curing

	Brand	Type
Post-Cure Unit	Juell 3D	Cure Cube 360

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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510(k) Summary K181220

October 3, 2018

Park Dental Research Corporation

2401 N. Commerce St. Suite E
Ardmore, OK 73401

800-243-7372

Contact Person: Dr. Ronald A Bulard

Trade Name: Juell 3D Volo Base

Common Name: Denture Base

Product Code: EBI

Regulation No.: 872.3760 Denture Relining, Repairing or Rebasing Resin

Classification: Class II

Predicate 510k: K162572 NextDent Denture/E-Denture from Vertex-Dental BV

Device Description:

Juell 3D Volo Base 3D-printing material is a light-cured resin indicated for the manufacturing of denture bases. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization.

3D printer is not included with the device.

Indications for Use:

Juell 3D Volo Base is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. Juell 3D Volo Base is intended exclusively for professional dental work. Fabrication of denture bases with Juell 3D Volo Base requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit.

Juell 3D Volo Base is compatible with the following CAD/CAM systems components:

Design

	Brand	Type
Scanner	Dental Wings	I series
Design Software	Dental Wings	DWOS

Printing

	Brand	Type	Software
Printer	Juell 3D	DLP	Flash OC

Post-Curing

	Brand	Type
Post-Cure Unit	Juell 3D	Cure Cube 360

Technological Characteristics:

Both Volo Base and NextDent Denture are mixtures of dimethacrylate resins with photo-initiator and pigments. The way they are used to make dentures is identical, using 3 D printers to form the dentures and UV light boxes for curing.

The results of this comparison demonstrate that the design, technology, materials, and composition of Juell 3D Volo Base are substantially equivalent to the predicate devices.

Mechanism of Action:

The mechanism of action is the same as the predicate devices and supports a determination of substantial equivalence. Dentures are used the same way by the patient no matter how they are formed. All types of denture are checked the same way for fit and the concerns regarding non-cured resin are the same no matter the type of curing.

Bench Testing:

Juell 3D Volo Base was tested for compliance with ISO 20795-1 Type 4 Material by testing the following: Flexural Strength, Flexural Modulus, Water Sorption, Water Solubility, and Residual Monomer. All test were passed. These same tests were passed by the predicate device except for water sorption which exceeded the value for Type 4 but passed for Type 2.

Biocompatibility Testing:

The constituents of Juell 3D Volo Base are very similar to the predicate device, NextDent Denture/E-Denture. This fact along with the very low level of residual monomer in the cured product meant no biocompatibility testing was done.

Predicate Device Comparison Table

	Juell 3D Volo Base	NextDent Denture/E-Denture
Regulation Number	21 CFR 872.3760	21 CFR 872.3760
Device Classification Name/Device Common Name	Denture Relining, Repairing or Rebasing Resin	Denture Relining, Repairing or Rebasing Resin
Product Code	EBI	EBI
Classification	II	II
Indications for use	Juell 3D Volo Base is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. Juell 3D Volo Base is intended exclusively for professional dental work. Fabrication of denture bases with Juell 3D Volo Base requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit.	NextDent Denture/E-Denture is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. NextDent Denture/E-Denture is intended exclusively for professional dental work. Fabrication of denture bases with NextDent Denture/E-Denture requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer and post-cure unit.
Device Description	Juell 3D Volo Base 3D-printing material is a light-cured resin indicated for the manufacturing of denture bases. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization. 3D printer is not included with the device.	NextDent Denture/E-Denture 3D-printing material is a light-cured resin indicated for the manufacturing of denture bases. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light curing box for final polymerization. 3D printer is not included with the device.

Material	Dimethacrylate resins	Dimethacrylate resins
Material Properties	Meets ISO 20795-1 for a Type 4 Material.	Meets ISO 20795-1 for a Type 4 material except for water solubility which meets the Type 2 criteria.

Conclusion:

Juell 3D Volo Base has the same Indications for Use and Device Description as the identified predicate device. Volo Base is as safe, as effective, and is substantially equivalent to the predicate device in regards to design, technological characteristics, mechanism of action, materials, performance test and biocompatibility.