March 30, 2021

EnvisionTEC GmbH
℅ Patsy Trisler
Regulatory Consultant
Qserve Group US, Inc.
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K203641
Trade/Device Name: E-Denture Pro
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: March 4, 2021
Received: March 8, 2021

Dear Patsy Trisler:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*

K203641

Device Name

EnvisionTEC E-Denture Pro

Indications for Use *(Describe)*

E-Denture Pro is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. E-Denture Pro is intended exclusively for professional dental work. Fabrication of denture bases with E-Denture Pro requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) 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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510(k) Summary – K203641

I. SUBMITTER	
Submitter Name:	EnvisionTEC GmbH
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Telephone:	+49 2043 987545
Date Prepared:	March 26, 2021

II. DEVICE	
Trade Name:	E-Denture Pro
Common Name	Denture Resin
Classification: **Name | Number** **Product Code** **Device Class**	 Denture Relining, Repairing, or Rebasing Resin | 21 CFR 872.3760 EBI II

III. PREDICATE DEVICE	
Primary Predicate Device:	K191497, NextDent Denture 3D+, Vertex-Dental BV
Reference Device	K102776, e-DENT Temporary Resin and Extra-Oral Curing System, DeltaMed GmbH

IV. INDICATIONS FOR USE STATEMENT

E-Denture Pro is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. E-Denture Pro is intended exclusively for professional dental work. Fabrication of denture bases with E-Denture Pro requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.

V. DEVICE DESCRIPTION

Device Identification	The E-Denture Pro system combines a scanner with design software, the light-curable resin, a 3D printer and a curing unit. These components are used together during the manufacture of the customized denture base for the removable full denture.
Technological Characteristics	The light-curable resin is a proprietary composition of acrylates, methacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes and absorbers. It is used by dental laboratories and dental practices to make the denture bases for removable full dentures.

	The resin is offered in lightproof 1 kg PE bottles along with a programmed chip (referred to as TAG), which is required for use with the 3D printer. The TAG contains information identifying the resin material, name and amount. E-Denture Pro resin is an alternative material to heat-curable and auto-polymerizable resins. EnvisionTECs Perfactory® 3D-Printer models designed and validated for use with the E-Denture Pro light cured resin are: EnvisionOne cDLM, with LED Vida Series, with LED P4K Series, with LED D4K Series, with LED

VI. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	NEW DEVICE	PRIMARY PREDICATE
510(k) NUMBER; DEVICE NAME; MANUFACTURER	K203641 E-Denture Pro EnvisionTEC GmbH	K191497 NextDent Denture 3D+ Vertex-Dental BV
PRODUCT CODE REGULATORY NAME CLASSIFICATION	EBI Denture Relining, Repairing, or Rebasing Resin 21 CFR 872.3760	EBI Denture Relining, Repairing, or Rebasing Resin 21 CFR 872.3760
INDICATIONS FOR USE	E-Denture Pro is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. E-Denture Pro is intended exclusively for professional dental work. Fabrication of denture bases with E-Denture Pro requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.	NextDent Denture 3D+ 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 3D+ is intended exclusively for professional dental work. Fabrication of denture bases with NextDent Denture 3D+ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following scanner, design software, additive printer and post-cure unit: Design: Scanner: 3Shape D900 Design Software: 3Shape Dental-System 2016 Premium Printing: Printer: 3D Systems NextDent 5100 Figure 4®; Software: 3D Sprint Post-curing: Post-cure unit: NextDent LC-3D Print Box

INGREDIENTS	Light-curable Resin	Light-curable Resin
MANUFACTURING TECHNOLOGY TYPE	Additive	Additive
PRODUCT CHARACTERISTICS:		
Sterility	Non-sterile	Non-sterile
Flexural Strength (comparative testing)	72.7 MPa	81.2 MPa
Secant Modulus (comparative testing)	2192 MPa	3113 MPa
Flexural Strain (comparative testing)	>5.0 % at break	2.8 % at break
Biocompatibility	Biocompatible, according to ISO 10993 testing	Biocompatible, according to ISO 10993 testing

VII PERFORMANCE AND SAFETY TESTING

Animal Testing:	This product category does not require animal testing.
Clinical Testing:	This product category does not require human clinical testing.
Laboratory Testing:	Testing was conducted to evaluate the performance of a manufactured denture base, according to requirements of DIN EN ISO 20795-1:2013, Dentistry – Base Polymers. Including biocompatibility requirements, the following specification requirements of the 3D-printed denture base material samples were tested and have been met: • Surface quality • Dimensional stability • Color and color stability • Translucency • Flexural strength and flexural modulus • Freedom from porosity • Bonding to synthetic teeth • Residual monomer • Sorption • Solubility
Shelf Life Testing:	Validated real-time shelf life of the E-Denture Pro resin at time of 510(k) submission is 3 months. The resin is on real-time validation testing for an ultimate shelf life of 24 months, stored in the original packaging at temperatures at 30º C. Properties being tested include material viscosity, material photoreactivity and color change. Resin also was tested for good transport stability.
Biocompatibility Testing:	Testing, according to ISO 10993 and Good Laboratory Practices, confirms that E-Denture Pro denture base is biocompatible and non-toxic and meets the requirements for a device in contact with mucosal membrane for >30 days. A biocompatibility risk assessment was developed and presented in the 510(k). As a result the following ISO 10993 tests were conducted and results

	met the requirements of each test: • Cytotoxicity Study Using ISO Elution Method (Part 5) • Guinea Pig Maximization Sensitization Test (Part 10) • Tests for Irritation and Skin Sensitization – Intracutaneous Injection in Rabbits (Part 10) • Acute Systemic Toxicity in Mice (Part 11)
Additive Manufacturing	Testing, according to FDA's guidance *Technical Considerations for Additive Manufactured Medical Devices*, was performed and results were provided in the 510(k). These tests included evaluation of all relevant properties of the printed resin using the permitted machines. Further, tests based on considerations of the orientation during manufacturing were performed.

VIII COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

The intended use, critical specifications, and additive method of manufacturing of E-Denture Pro are substantially equivalent to the predicate device, NextDent Denture 3D+.

While the resin of the predicate is different from E-Denture Pro, both are photo-curable resins used in additive manufacturing and are of the same material category, and the software is the same as used in 3D-printing the Reference device.

The additive manufacturing processes both use a resin, scanner, printer and curing unit.

The testing performed by EnvisionTEC, directly compared to the predicate produced results that are similar to the predicate.

The noted differences, in comparison to the predicate device, raise no new questions of safety and effectiveness.

VIX CONCLUSION

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded E-Denture Pro is substantially equivalent to the predicate device. EnvisionTEC's analysis of E-Denture Pro compared to the predicate show they have the same intended use, and technological parameters that meet the requirements of ISO 20795-1:2003.