May 25, 2021

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

Re: K210977
Trade/Device Name: E-Dent 1000
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBI, ELM
Dated: March 29, 2021
Received: April 1, 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 and ENT 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)*
K210977

Device Name

E-Dent 1000

Indications for Use *(Describe)*

E-Dent 1000 is a light-curable resin indicated for the fabrication of:
• individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area,
• individual and fixed single veneers,
• artificial teeth for dental prostheses, which are used for removable permanent full dentures,
• individual and removable monolithic full and partial dentures
in dental laboratories. The material is an alternative to traditional restorative dental material. E-Dent 1000 is intended exclusively for professional dental work. Fabrication of dental applications with E-Dent 1000 requires a computer aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression, or in case of artificial teeth for dental prostheses the digital dental files based on manufacturer's data, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER	
Submitter Name:	EnvisionTEC GmbH
Submitter Address:	Bruesseler Straße 51 D-45968 Gladbeck Germany
Contact Person: Email:	Ruediger van Bernum, Head of Application ruediger.v.bernum@envisiontec.de
Telephone:	+49 2043 9875 45
Date Prepared:	March 29, 2021

II. DEVICE			
Trade Name:	E-Dent 1000		
Common Name	Tooth shade resin material, Denture relining, repairing, rebasing resin, Preformed plastic denture tooth		
Classification Numbers | Names **Product Codes** **Device Class**	21 CFR 872.3690 Material, Tooth Shade, Resin EBF II	21 CFR 872.3760 Resin, Denture, Relining, Repairing, Rebasing EBI II	21 CFR 872.3590 Denture, Plastic, Teeth ELM II, 510(k)-Exempt

III. PREDICATE DEVICE	
Predicate Devices	
Primary Predicate	K201668, VarseoSmile Crown Plus, BEGO Bremer Goldschlagerei Wilh. Herbst GmbH & Co. KG (EBF product code)
Secondary Predicate	K151142, IvoBase CAD for Zenotec, IvoBase CAD Bond and Modelling Liquid, Ivoclar Vivadent, Inc. (EBI product code)
Reference Device(s)	K102776: e-DENT Temporary Resin and Extra-Oral Curing System, DeltaMed GmbH

IV. INDICATIONS FOR USE STATEMENT

E-Dent 1000 is a light-curable resin indicated for the fabrication of:

- individual and fixed permanent full single crowns, permanent partial crowns in front and posterior area,
- individual and fixed single veneers,
- artificial teeth for dental prostheses, which are used for removable permanent full dentures,
- individual and removable monolithic full and partial dentures

in dental laboratories. The material is an alternative to traditional restorative dental material. E-Dent 1000 is intended exclusively for professional dental work. Fabrication of dental applications with E-Dent 1000 requires a computer aided and manufacturing (CAD/CAM) system that includes the following components: digital dental files based on a digital impression or in case of artificial teeth for dental prostheses the digital dental files

based on manufacturer's data, a digital light processing (DLP) printer, and curing light equipment.

V. DEVICE DESCRIPTION

Device Identification	The E-Dent 1000 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 E-Dent 1000 restorative dental products.
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 to make the customized temporary crowns and bridges for patients who need restoration of their natural teeth. E-Dent 1000 is available in six different colors. The resin is packaged in lightproof 1 kg PE bottles along with a programmed RFID chip (referred to as TAG), which is required for use with the validated 3D printers. The TAG contains information identifying the resin material, name and amount. E-Dent 1000 resin is an alternative material to heat-curable and auto-polymerizable resins. EnvisionTECs Perfactory® 3D-Printer DLP models designed and validated for use with the E-Dent 1000 light cured resin are: • EnvisionOne cDLM, with LED • Micro series, with LED • Vida Series, with LED • P4K Series, with LED • D4K Series, with LED

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 crowns, artificial teeth, veneers and dentures, according to requirements of: • DIN EN ISO 10477:2018: *Dentistry—Polymer-based crown and veneering materials (type 2, class II)* • DIN EN ISO 4049:2019-09: *Dentistry—Polymer-based restorative materials (type 1, class II, group 2)*, • DIN EN ISO 7491: *Dental materials—Determination of colour stability*. • DIN EN ISO 20795-1:2009-02 *Dentistry–Resins Part 1: Prosthetic resins.* Including biocompatibility requirements, the following specification requirements of the 3D-printed 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 • Water Sorption • Water Solubility
Shelf Life Testing:	Validated accelerated shelf life testing of the E-Dent 1000 resin at time of 510(k) submission is 4 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. The E-Dent 1000 resin also was tested for good transport stability.
Biocompatibility Testing:	A biocompatibility risk assessment was developed and presented in the 510(k). As a result, the following ISO 10993 tests were conducted according to Good Laboratory Practices. Testing showed the E-Dent 1000 printed and tested samples are biocompatible and non-toxic and meet the requirements for a device in contact with mucosal membrane for >30 days. • 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 Study 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, technological characteristics and critical specifications, are similar to both Predicate devices. The additive method of manufacturing E-Dent 1000 is similar to Primary Predicate.

The intended use of fabrication of dental prosthetics is the same as both Predicates. The manufacture of the permanent crowns and veneers is the same as the Primary Predicate, K201668. The manufacture of the removable dentures is the same as the Secondary Predicate, K151142. The manufacture of artificial teeth is Class II, but 510(k)-exempt (product code ELM), therefore no Predicate is necessary.

While the E-Dent 1000 resin is different from Primary Predicate resin, each is a photo-

curable resin used in additive manufacturing of dental restorative devices and are of the same material category.

The Reference device, K102776, is presented because of similar technological characteristics to E-Dent 1000; it also is a photo-curable resin and the 3D printer and associated software are the same as used for E-Dent 1000.

The additive manufacturing processes for Primary Predicate and Reference devices use a photo-curable resin, scanner, 3D printer, curing unit and associated validated software.

The noted differences, in comparison to the Predicate devices, 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-Dent 1000 substantially equivalent to the Predicate devices. EnvisionTEC's analysis of E-Dent 1000 shows it has the same intended use, and technological parameters that meet the requirements of ISO 20795-1:2009-02.