June 14, 2021

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

Re: K211101
Trade/Device Name: E-Temp
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: April 9, 2021
Received: April 20, 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 -S

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)*
K211101

Device Name

E-Temp

Indications for Use *(Describe)*

E-Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns and temporary bridges in dental laboratories. The material is an alternative to traditional restorative dental material. E-Temp is intended exclusively for professional dental work. Fabrication of dental applications with E-Temp 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.

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K211101 510(k) Summary

I. SUBMITTER	
Submitter Name:	EnvisionTEC GmbH
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Telephone:	+49 2043 9875 45
Date Prepared:	9 April 2021
II. DEVICE	
Trade Name:	E-Temp
Common Name	Temporary Crown and Bridge Resin
Classification **Number | Name:** **Product Code** **Device Class**	21 CFR 872.3770 Crown and Bridge, Temporary, Resin EBG II
III. PREDICATE DEVICE	
Primary Predicate Device	K102776, e-DENT Temporary Resin and Extra-Oral Curing System, DeltaMed GmbH
Reference Device	None

IV. INDICATIONS FOR USE STATEMENT

E-Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns and temporary bridges in dental laboratories. The material is an alternative to traditional restorative dental material. E-Temp is intended exclusively for professional dental work. Fabrication of dental applications with E-Temp 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-Temp 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 temporary crowns or bridges.
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-Temp 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-Temp 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-Temp 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 manufactured temporary crowns and bridges, 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*. 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-Temp 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-Temp 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 by a 3rd party contract laboratory. Testing showed the E-Temp 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, critical specifications, and additive method of manufacturing of E-Temp are substantially equivalent to the Predicate device.

While the E-Temp resin is different from the Predicate resin, both are photo-curable resins used in additive manufacturing and are of the same material category; and both use the same 3D printer and associated validated software.

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-Temp is substantially equivalent to the predicate device. EnvisionTEC's analysis of E-Temp show they have the same intended use, and similar technological parameters according to the characterization testing.