November 27, 2020

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

Re: K201173
Trade/Device Name: E-Guard
Regulatory Class: Unclassified
Product Code: MQC, EBI
Dated: August 27, 2020
Received: August 31, 2020

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,

For Srinivas “Nandu” Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201173

Device Name

E-Guard

Indications for Use *(Describe)*

EnvisionTEC's E-Guard is a light-cured resin. It is a polymer used to create removable structures for therapeutic restorations, i.e. bite guards/splints and occlusal night guard/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.

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.

K201173
510(k) Summary

I. SUBMITTER	
Submitter Name:	EnvisionTEC GmbH
Submitter Address:	Brusseler Straße 51 D-45968 Gladbeck Germany
Contact Person: Email:	Ruediger van Bernum, Head of Application ruediger.v.bernum@envisiontec.de
Date Prepared:	November 25, 2020

II. DEVICE		
Trade Name:	E-Guard	
Common Name	Mouthguard, Prescription; Dental Resin	
Regulatory Name **Classification** **Product Codes**	Mouthguard, Prescription Unclassified MQC	Resin, Denture, Relining, Repairing, Rebasing 21 CFR 872.3760, Class 2 EBI

III. PREDICATE DEVICE	
Primary Predicate Device:	K190107: VeriSplint, Whip Mix Corporation
Reference Device Information:	K102776: e-DENT Temporary Resin and Extra-Oral Curing System, DeltaMed GmbH [Product Code: EBG, Temporary Crown and Bridge Resin, 21 CFR 872.3770]

IV. INDICATIONS FOR USE STATEMENT

EnvisionTEC's E-Guard is a light-cured resin. It is a polymer used to create removable structures for therapeutic restorations, i.e. bite guards/splints and occlusal night guard/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.

V. DEVICE DESCRIPTION	
Device Identification	The E-Guard system combines a scanner with design software, the light-cured resin, a 3D printer and a curing unit. These components are used together during the manufacture of the dental appliance splint/bite guard.
Technological Characteristics	The light-curing resin is composed of acrylate/methacrylate, methacrylated oligomers and monomers, photo initiators, colorants/dyes and absorbers. It is used by dental laboratories and dental practices to make customized bite splints, using the 3D-printer.

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.

The E-Guard resin is an alternative material to heat-cured and auto-polymerizing resins.

EnvisionTECs Perfactory® DDP (Digital Dental Printer) models designed for use with the E-Guard light cured resin are:

Printers with bulb

Perfactory® DDP4 XL
Perfactory® Desktop DDP plus
Perfactory® Desktop Pixera plus
Perfactory® DDP4 M
Perfactory® DDP Mini
Perfactory® DDP Mini XL

Printers with LED

Perfactory® Vida 2
Perfactory® Vida 2 Hi-RES
Perfactory® Vida HD cDLM
Perfactory® Vida cDLM
Perfactory® P4K 35,62,75,90
Perfactory® MicroPlusXL
Perfactory® EnvisionOne cDLM

VI. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	NEW DEVICE	PRIMARY PREDICATE
510(k) NUMBER; DEVICE NAME; MANUFACTURER	Not yet assigned E-Guard EnvisionTEC GmbH	K190107 VeriSplint Whip Mix Corporation
PRODUCT CODE **REGULATORY NAME** **CLASSIFICATION (21 CFR)**	MQC / EBI Prescription Mouthguard / Resin, Denture Unclassified / 872.3760 Class II	MQC / EBI Prescription Mouthguard / Resin, Denture Unclassified / 872.3760 Class II
INDICATIONS FOR USE	E-Guard is a light-cured resin. It is a polymer used to create removable structures for therapeutic restorations, i.e. bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.	Whip Mix VeriSplint is a light-cured resin. It is an orthodontic base polymer used to create removable structures for therapeutic restorations like bite guards/splints and occlusal night guards/splints using the Additive Manufacturing process. The resin in combination with a scanner, printer, and curing unit make up the system.
INGREDIENTS	Light-cured Resin	Light-cured Resin
MANUFACTURING TECHNOLOGY TYPE	Additive	Additive

PRODUCT CHARACTERISTICS:		
Sterility	Non-sterile	Non-sterile
Water Solubility	0.5 ug/mm^3	< 1 ug/mm^3
Water Sorption	37 ug/mm^3	29 ug/mm^3
Bending Strength	Testing of 2 samples, same lot: (1) 85.1 MPa; (2) 79.4 MPa	> 100 MPa
Bending Modulus	Testing of 2 samples, same lot: (1) 2130 MPa; (2) 2052 MPa	> 2500 MPa
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 bite splint, according to requirements of DIN EN ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic base polymers. The requirements for flexural strength, flexural modulus, water solubility and water sorption content were met.
Shelf Life Testing:	The resin has been validated real time for a shelf life of 1 year, stored in the original packaging at temperatures between 5º to 30º C. Properties tested include: material viscosity, material reactivity, material homogeneity and color change.
Biocompatibility Testing:	Testing, according to ISO 10993, confirms that E-Guard is biocompatible and non-toxic and meets the requirements for a device in contact with mucosal membrane for >30 days.
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 DEVICE

The intended use, critical specifications, and additive method of manufacturing of E-Guard are substantially equivalent to the predicate device, VeriSplint.

While the resin of the predicate is different from E-Guard, both are photo-curable resins used in additive manufacturing and are of the same material category. The additive manufacturing processes both use a resin, scanner, printer and curing unit.

The testing performed by EnvisionTEC, compared to that reported for the predicate, Whip Mix, produced results that are similar to the predicate.

In addition, the E-Guard also is similar technologically to the reference device: K102776, DeltaMed e-DENT, which uses a photo-curable resin, similar design software and scanner, as well as the same type of printer software and 3D-printer.

The noted differences, in comparison to the predicate device, raise no new questions.

VIX CONCLUSION

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded E-Dent is substantially equivalence to VeriSplint predicate device. EnvisionTEC's analysis of E-Guard compared to the predicate show they have the same intended use, and the technological parameters meet the requirements of ISO 20795-2:2003.