June 10, 2022

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

Re: K220894
Trade/Device Name: SmileGuard
Regulatory Class: Unclassified
Product Code: MQC, KMY
Dated: March 22, 2022
Received: March 28, 2022

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K220894

Device Name

SmileGuard™

Indications for Use *(Describe)*

SmileGuard™ light curable resin is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards and splints.

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

I. SUBMITTER

Submitter Name:	EnvisionTEC GmbH
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Telephone:	+49 2043 9875 45
Date Prepared:	22 March 2022

II. DEVICE

Trade Name:	SmileGuard™	
Common Name	Mouthguard, Prescription	
Regulatory Name **Classification** **Product Codes**	Mouthguard, Prescription Unclassified MQC	Positioner, Tooth, Preformed 21 CFR 872.5525, Class 1 KMY

III. PREDICATE DEVICE

Primary Predicate Device:	K183598, KeyPrint® KeySplint Soft™, Keystone Industries

IV. INDICATIONS FOR USE STATEMENT

SmileGuard™ light curable resin is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards and splints.

V. DEVICE DESCRIPTION

Device Identification **and** **Technological Characteristics**	The SmileGuard™ system combines the light-curable resin, for use with a scanner with design software, validated 3D printer and a curing unit. These components are used together during the additive manufacture of dental appliance splints/mouth guards. The light-curing resin is a proprietary composition 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 filled in lightproof 1 kg PE bottles labeled and offered together with a programmed RFID chip (referred to as TAG), which is required for use with the validated EnvisionTEC 3D printers. The TAG contains information identifying the resin: material, name and amount.

	The SmileGuard™ resin is an alternative material to heat-curing and auto-polymerizing resins. EnvisionTEC's 3D printer models designed for use with the SmileGuard™ light-curing resin are: **Printers with bulb** Perfactory® DDP4 **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 Perfactory® D4K

VI. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

	NEW DEVICE	PRIMARY PREDICATE
510(k) NUMBER; DEVICE NAME; MANUFACTURER	Not yet assigned SmileGuard™ EnvisionTEC GmbH	K183598 KeyPrint® KeySplint Soft™ Keystone Industries
PRODUCT CODE REGULATORY NAME CLASSIFICATION (21 CFR)	MQC Mouthguard, Prescription Unclassified KMY Positioner,Tooth, Preformed 872.5525, Class 1	MQC Mouthguard, Prescription Unclassified KMY Positioner,Tooth, Preformed 872.5525, Class 1
INDICATIONS FOR USE	SmileGuard™ light curable resin is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards and splints.	The KeyPrint® KeySplint Soft™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.
INGREDIENTS	Light-curing Resin	Light-curing Resin
MANUFACTURING TECHNOLOGY TYPE	Additive	Additive
Sterility	Non-sterile	Non-sterile
Biocompatibility	Biocompatible, according to ISO 10993 testing	Biocompatible, according to ISO 10993 testing
PRODUCT CHARACTERISTICS:	Sample conditioned for 24 hr after printing:	
Tensile Strength	19.1 +/- 2.5 MPa [per ISO 527]	Unknown
Tensile Modulus	319 +/- 48 MPA [per ISO 527]	Unknown

Elongation at break	138 +/- 16% [per ISO 527}	>110% [Ref ASTM D638; pass, per design requirements]
Ultimate Flexural Strength	37.3 +/- MPa [per ASTM D790]	44-47 MPa [Ref ASTM D790; pass, per design requirements]
Ultimate Flexural Modulus	1,107 +/- 37 MPa [per ASTM D790]	1,100-1,400 MPa [Ref ASTM D790; pass, per design requirements]
IZOD Impact (notched)	70.7 +/- 12.1 J/m [per ASTM D256, method A]	45-48 J/m [Ref ASTM D256; pass, per design requirements]
Shore D hardness	76 +/- 2% [per ASTM D2240]	80-85 MPa [Ref ASTM D2240; pass per design requirements]

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 of above characteristics was conducted to evaluate the performance of the printed splint, according to requirements of DIN EN ISO 20795-2:2013, *Dentistry – Base Polymers – Part 2: Orthodontic base polymers* and according to DIN EN ISO 527-1, *Plastics – Determination of Tensile Properties*. All requirements were met.
Shelf Life Testing:	The resin has been validated real time for a shelf life of 18 months, stored in the original packaging at temperatures between 5º to 30º C. Resin properties evaluated included: viscosity, photoreactivity, and visual inspection of color change.
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 an independent laboratory. The testing demonstrated that SmileGuard™ 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 Studies Using ISO Elution Method (Part 5) • Guinea Pig Maximization Sensitization Test (Part 10) • Intracutaneous Tests for Irritation and Skin Sensitization in Rabbits (Part 10)
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 TO THE PREDICATE DEVICE OF TECHNOLOGICAL CHARACTERISTICS

The intended use, critical specifications, and additive method of manufacturing SmileGuard™ resin are substantially equivalent to the Predicate device.

While the SmileGuard™ proprietary resin is different from the Predicate, both are light-curable acrylate/methacrylate resins used in additive manufacturing and are of the same material category, commonly used for fabricating customized dental splints. The additive manufacturing processes both use the named resins, and validated scanners, printers and curing units.

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

VIX CONCLUSION

EnvisionTEC's analysis of SmileGuard™ compared to the Predicate show they have the same intended uses, and the technological parameters which are similar and meet the requirements of ISO 20795-2:2003, and ISO 527-1.

Based on the comparisons provided and the data submitted in this 510(k), it can be concluded the SmileGuard™ resin is substantially equivalence to the Predicate KeyPrint® KeySplint Soft™ resin device.