September 3, 2021

DMG Digital Enterprises SE
% Pamela Papineau
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Ave
Ayer, Massachusetts 01432

Re: K210940
Trade/Device Name: LuxaPrint Ortho Plus
Regulatory Class: 21 CFR 872.3760
Product Code: MQC, EBI
Dated: June 7, 2021
Received: June 8, 2021

Dear Pamela Papineau:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210940

Device Name

LuxaPrint Ortho Plus

Indications for Use *(Describe)*

Fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and positioners.

The product is for use with DLP / SLA printers that work at wavelengths of 385 nm or 405 nm.

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.

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Attachment C – LuxaPrint Ortho Plus 510(k) Summary

General Information

Preparation date:	02 September 2021
Owner's Name:	DMG Dental Enterprises SE (FDA Registration 3012623144)
Address:	Elbgaustrasse 248 22547 Hamburg Germany
Telephone Number:	011-49-40-84006-0
Fax Number:	011-49-40-84006-222
Contact Person:	Stephan Schaefer
Subject Device Name:	LuxaPrint Ortho Plus
Trade Name:	LuxaPrint Ortho Plus
Common/Usual Name:	Prescription Mouthguard
Product Code; Regulation:	MQC (Mouthguard, Prescription); no associated regulation EBI (Resin, Denture, Relining, Repairing, Rebasing); 21 CFR 872.3760
Device Classification:	Unclassified
Primary Predicate Device:	
Trade Name:	EnvisionTEC GmbH E-Guard
Common/Usual Name:	Prescription Mouthguard
Product Code; Regulation:	MQC (Prescription Mouthguard); no associated regulation EBI (Resin, Denture, Relining, Repairing, Rebasing); 21 CFR 872.3760
Device Classification:	Unclassified
Premarket Notification:	K201173, SE date 27 November 2020

Device Description

LuxaPrint Ortho Plus is a (meth)acrylate-based photocurable polymer resin indicated for use for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and positioners, using a 3D printing process. LuxaPrint Ortho Plus material is used in a dental laboratory to fabricate a removable custom dental appliance. LuxaPrint Ortho Plus will be available in two variants matched to the operating wavelength of the 3D printer (385 nm and 405 nm). LuxaPrint Ortho Plus is used in conjunction with a compatible dental

scanner, 3D printer, and curing equipment. Typical medical indications include bruxism and teeth grinding, or stabilization of the tooth's position after active orthodontic treatment.

Indications for Use
For the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and positioners. The product is for use with DLP/SLA printers that work at wavelengths of 385 nm or 405 nm.

Substantial Equivalence / Comparison of Technical Characteristics with the Predicate Device
The predicate device is the EnvisionTEC GmbH E-Guard cleared in K201173. A summary comparison of the subject and predicate device systems is provided in the substantial equivalence table below.

Substantial Equivalence Comparison Table

Attribute	Proposed Device DMG Digital Enterprises SE LuxaPrint Ortho Plus (current submission)	Predicate Device EnvisionTEC GmbH E-Guard (K201173)	Similarities and Differences
Common Name	Prescription Mouthguard	Prescription Mouthguard	Same
Classification Name	Unclassified	Unclassified	Same
Device Class	Unclassified	Unclassified	Same
Regulation	N/A, 21 CFR 872.3760	N/A, 21 CFR 872.3760	Same
Regulation Name	Mouthguard, Prescription Resin, Denture, Relining, Repairing, Rebasing	Mouthguard, Prescription Resin, Denture, Relining, Repairing, Rebasing	Same
Product Code	MQC, EBI	MQC, EBI	Same
Indications for Use	Fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and positioners. The product is for use with DLP / SLA printers that work at wavelengths of 385 nm or 405 nm.	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.	Same with wording differences

Attribute	Proposed Device DMG Digital Enterprises SE LuxaPrint Ortho Plus (current submission)	Predicate Device EnvisionTEC GmbH E-Guard (K201173)	Similarities and Differences
Use Environment	Dental office/clinic, dental laboratory for appliance design and fabrication; home use for the resulting dental appliance.	Dental office/clinic, dental laboratory for appliance design and fabrication; home use for the resulting dental appliance.	Same
Material Composition	Photocurable (meth)-acrylate-based polymer resin	Photocurable (meth)-acrylate-based polymer resin	Same
Principle of Operation	The device consists of raw material that is used to fabricate removable custom dental appliances, such as orthodontic splints and/or mouthguards. The finished devices can be used to support tooth stabilization following active orthodontic treatment, and/or for the relief of bruxism or snoring. The device is used in conjunction with a compatible scanner, 3D printer, and curing unit.	The device consists of raw material that is used to fabricate removable custom dental appliances, such as orthodontic splints and/or mouthguards. The finished devices can be used to support tooth stabilization following active orthodontic treatment, and/or for the relief of bruxism or snoring. The device is used in conjunction with a compatible scanner, 3D printer, and curing unit.	Same
Water Solubility	1.5 – 3.6 µg/mm³ (385 nm) 0.7 – 2.1 µg/mm³ (405 nm)	0.5 µm/mm³	Equivalent; both meet ISO 4049 & ISO 20795-2 requirements
Water Sorption	18.6 – 20.3 (385 nm) 17.1 – 17.7 µg/mm³ (405 nm)	37 µm/mm³	Equivalent; both meet ISO 4049 & ISO 20795-2 requirements
Flexural Strength	80 – 93 MPa (385 nm) 77 – 90 MPa (405 nm)	79 – 85 MPa	Equivalent; both meet ISO 4049 & ISO 20795-2 requirements
Flexural Modulus	1.9 – 2.4 GPa (385 nm) 2.1 – 2.5 GPa (405 nm)	2052 – 2130 MPa	Equivalent; both meet ISO 4049 & ISO 20795-2 requirements

Attribute	Proposed Device DMG Digital Enterprises SE LuxaPrint Ortho Plus (current submission)	Predicate Device EnvisionTEC GmbH E-Guard (K201173)	Similarities and Differences
Biocompatibility	ISO 10993	ISO 10993-1 Biocompatibility Assessment ISO 10993-5 Cytotoxicity ISO 10993-10 Irritation ISO 10993-10 Sensitization ISO 10993-3 Genotoxicity	Equivalent
Single Use / Reusable	Single Use	Single Use	Same
Sterilization / Reprocessing	Non-sterile device; no reprocessing requirements	Non-sterile device; no reprocessing requirements	Same
Software	Device does not contain software	Device does not contain software	Same
Electrical Safety & EMC	Not applicable	Not applicable	Same
Compatible 3D Printer Type	DLP / SLA operating at 385 nm or 405 nm	DLP / SLA operating at 385 nm	Different

Non-clinical Performance Testing

Performance data demonstrated that finished devices manufactured using the LuxaPrint Ortho Plus material meet all predetermined acceptance criteria contained in the product specification and are suitable for use in the fabrication of reusable orthodontic splints and mouthguards. 3D printed devices fabricated using LuxaPrint Ortho Plus have been tested for and found to have comparable physical properties appropriate for removable dental appliances flexural strength, flexural modulus, water solubility, and water sorption. The risks associated with the use of the new devices were found acceptable when evaluated in accordance with ISO 14971. Risks and benefits associated with the proposed and the predicate device are the same. Design verification and validation activities consisted of physical testing, biocompatibility evaluation, and stability (shelf life) validation.

Comparison of Technological Characteristics with the Predicate Device

The intended use, performance specifications, and additive method of manufacturing of LuxaPrint Ortho Plus are substantially equivalent to the predicate device, E-Guard. While the specific resin formulation of the predicate is different from LuxaPrint Ortho Plus, both are (meth)acrylate-based 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 on LuxaPrint Ortho Plus produced results similar to data reported for the predicate device. Although the wording is not identical, the indications for use

for LuxaPrint Ortho Plus are equivalent to those of the predicate E-Guard in that both devices are intended for the fabrication of removable dental appliances such as mouthguards, nightguards, splints, and positioners. The LuxaPrint Ortho Indications for Use further state "the product is for use with DLP / SLA printers that work at wavelengths of 385 nm or 405 nm," while the predicate Indications for Use states "the resin in combination with a scanner, printer, and curing unit make up the system". The specific 3D printer units recommended for use with LuxaPrint Ortho Plus are prominently identified in the device Instructions for Use. The predicate device Indications for Use statement identifies E-Guard as "a light-cured resin". The same information is presented in the LuxaPrint Ortho Plus Instructions for Use under the heading "Product Description." These minor differences do not adversely affect substantial equivalence.

Conclusion

The DMG Dental Enterprises SE LuxaPrint Ortho Plus meets all the pre-determined acceptance criteria of the testing performed to confirm substantial equivalence to the predicate device.