May 12, 2023

Harvest Dental Products, LLC
Colleen Boswell
Regulatory Affairs Consultant
905 Columbia Street
Brea, California 92821

Re: K222489
Trade/Device Name: Harvest Printable Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, ELM, MQC
Dated: April 25, 2023
Received: April 25, 2023

Dear Colleen Boswell:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., CQIA
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.

Submission Number *(if known)*

K222489

Device Name

Harvest Printable Resin

Indications for Use *(Describe)*

Harvest Printable Resin is indicated for the fabrication of dental bases for full removable dentures, artificial teeth, dental bite splints and guards and try-in devices, i.e., denture base and teeth. The material is an alternative to traditional heat-curable and auto-polymerizing resins and is intended for professional dental work only. This material is intended to be used by dental lab technicians and approved by licensed practitioners before being provided to the patient.

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 **K222489**

1. Submitter:

Harvest Dental Products, LLC
905 Columbia Street
Brea, California 92821

Contact Person: Colleen Boswell
Telephone Number: (714) 674-7400
Fax Number: (714) 674-7402

Date Prepared: April 23, 2023

2. Device:

Name of Device: Harvest Printable Resin
Common Name: Denture relining, repairing, rebasing resin
Denture, plastic teeth
Prescription mouthguard

Classification Name/ Device Classification/ Device Class/ Product Code: Denture Relining, Repairing, or Rebasing Resin, per 21 CFR 872.3760, II, EBI (Primary classification)
Denture, Plastic, Teeth, per 21 CFR § 872.3590, II, ELM
Unclassified (Mouthguard), MQC

3. Predicate Device:

Primary Predicate: *NextDent Denture/E-Denture,* Vertex-Dental B.V., K162572, Product Code EBI

Secondary Predicate: *E-Guard,* EnvisionTEC GmbH, K201173, Product Code MQC, EBI

4. Device Description

Harvest Printable Resin is a light-cured resin developed for additive manufacturing (3D printing) of individual full denture bases, artificial teeth, bite splints and guards and try-in devices, i.e., denture base and teeth. After being utilized in a 3D stereolithographic printer to generate a dental device based on a solid model, the device is placed in a UV light curing unit for final polymerization.

Fabrication using **Harvest Printable Resin** requires an appropriate computer-aided Design and Manufacturing (CAD/CAM) system, a digital light processing (DLP) printer, and post-processing light curing equipment. It has been optimized for use with Asiga (Max UV, Pro 4K65 and Pro 4K80) and Sprintray (Pro95 S and Pro55 S) printers and, therefore, may only be used in conjunction with these printers and their associated software systems. It is also only to be used in conjunction with Asiga (Max UV, Pro 4K65 and Pro 4K80) and Sprintray (Procure and Procure 2) curing units for post-processing.

The 3D printer is not included with the device.

5. Statement of Indications for Use:

Harvest Printable Resin is indicated for the fabrication of dental bases for full removable dentures, artificial teeth, dental bite splints and guards and try-in devices, i.e., denture base and teeth. The material is an alternative to traditional heat-curable and auto-polymerizing resins and is intended for professional dental work only. This material is intended to be used by dental lab technicians and approved by licensed practitioners before being provided to the patient.

6. Summary of Technological Characteristics with the Predicate Device

The technological characteristics of the subject **Harvest Printable Resin** is similar to the predicate devices, NextDent Denture/E-Denture (K162572) and E-Guard (K201173). There are no substantial technical or functional differences between the **Harvest Printable Resin** and the predicate devices in terms of chemical composition, function and intended use. All are light-cured resins used in a 3D printer which prints the shape determined by a 3D stereolithographic drawing. See Table 1 below for technological characteristics and comparisons of the denture relining, repairing, rebasing resin, plastic denture teeth resin and prescription mouthguard and splints resin.

Table 1: Comparison of Subject and Predicate Devices

Element	Harvest Printable Resin (Proposed Device)	NextDent Denture/ E-Denture (Primary Predicate)	E-Guard (Secondary Predicate)	Comparison
Manufacturer	Harvest Dental Products, LLC	Vertex-Dental B.V.	EnvisionTEC GmbH	N/A
510(k)	K222489	K162572	K201173	N/A
Target Users	Dental laboratories	Healthcare facility/hospital, dental (technical) laboratory	Dental laboratories and dental practices	Same
Common Name	Printable Resin	Printable Resin	Printable Resin	Same
Device Description	**Harvest Printable Resin** is light-cured resin developed for additive manufacturing (3D printing) of individual full denture bases, artificial teeth, bite splints and guards and try-in devices, i.e., denture base and teeth. After being utilized in a 3D stereolithographic printer to generate a dental device based on a solid model, the device is placed in a UV light	NextDent Denture/ E-Denture 3D-printing material is a light-cured resin indicated for the manufacturing of denture bases. The material is used in a 3D printer, which prints the shape determined by a 3D stereolithographic drawing. After printing, the printed product is placed in a UV-light	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. The light-curing resin is composed of acrylate/	Same. The resins are used in the 3D printing of dental devices including denture bases, bite splits and guards. **Note:** Artificial teeth are 510(k) exempt and the

Element	Harvest Printable Resin (Proposed Device)	NextDent Denture/ E-Denture (Primary Predicate)	E-Guard (Secondary Predicate)	Comparison
	curing unit for final polymerization. Fabrication using **Harvest Printable Resin** requires an appropriate computer-aided Design and Manufacturing (CAD/CAM) system, a digital light processing (DLP) printer, and post-processing light curing equipment. It has been optimized for use with Asiga (Max UV, Pro 4K65 and Pro 4K80) and Sprintray (Pro95 S and Pro55 S) printers and, therefore, may only be used in conjunction with these printers and their associated software systems. It is also only to be used in conjunction with Asiga (Max UV, Pro 4K65 and Pro 4K80) and Sprintray (Procure and Procure 2) curing units for post-processing. The 3D printer is not included with the device.	curing box for final polymerization. 3D printer is not included with the device.	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 1kg 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: Perfactory DDP4 XL; Perfactory Desktop DDP plus; Perfactory Desktop Pixera plus; Perfactory DDP4 M; Perfactory DDP Mini; Perfactory DDP Mini XL; Perfactory Vida 2; Perfactory Vida 2 Hi-RES; Perfactory Vida HD cDLM; Perfactory Vida cDLM; Perfactory P4K 35, 62, 75, 90; Perfactory	reason for no predicate for this indication.

Element	Harvest Printable Resin (Proposed Device)	NextDent Denture/ E-Denture (Primary Predicate)	E-Guard (Secondary Predicate)	Comparison
			MicroPlusXL; Perfactory EnvisionOne cDLM.	
Indications For Use	**Harvest Printable Resin** is indicated for the fabrication of dental bases for full removable dentures, artificial teeth, dental bite splints and guards and try-in devices, i.e., denture base and teeth. The material is an alternative to traditional heat-curable and auto-polymerizing resins and is intended for professional dental work only. This material is intended to be used by dental lab technicians and approved by licensed practitioners before being provided to the patient.	NextDent Denture/ E-Denture is a light-cured resin indicated for the fabrication of denture bases fabricated in dental laboratories, including full and partial removable dentures. The material is an alternative to traditional heat cured and auto polymerization resins. NextDent Denture/ E-Denture is intended exclusively for professional dental work. Fabrication of denture bases with NextDent Denture/ E-Denture requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer, and post-cure unit. NextDent Denture/ E-Denture is compatible with the following CAD/CAM systems components - 3Shape D900 scanner, 3Shape Dental-System 2016-Premium design software, EnvisionTEC DDP 4 printer using Perfactory software, Rapidshape D30 printer using NetFabb software, Micraft 125Y printer using MiiUtility MiiController software, 3D systems Figure 4 printer using 3D Sprint software, Roland DG DWP-80S Printer using Ver1.1 software,	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.	The resins are indicated for use in printing denture bases and/or as custom bite splints and guards. **Note:** Artificial teeth are 510(k) exempt and the reason for no predicate for this indication.

Element	Harvest Printable Resin (Proposed Device)	NextDent Denture/ E-Denture (Primary Predicate)	E-Guard (Secondary Predicate)	Comparison
		and NextDent LC-3DPrint Box post-curing unit.		
Curing Mechanism	Light-cure	Light-cure	Light-cure	Same
Technique	Additive Manufacturing (3D printing)	Additive Manufacturing (3D printing)	Additive Manufacturing (3D printing)	Same
Basic Chemical Composition	Methacrylates, urethane methacrylates, photo initiators and pigments	Dimethacrylate-based resins with photo-initiator and pigments	Acrylates, methacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes and absorbers.	Similar - All methacrylate-based light-cure resins with colorants and photo initiators.
Ultimate Flexural Strength (ISO 20795-1)	81.6 MPa **≥ 65 MPa**	84 MPa **≥ 65 MPa**	N/A	Same - Passed ISO 20795-1 requirements
Ultimate Flexural Strength (ISO 20795-2)	81.6 MPa **≥ 50 MPa**	N/A	79.4 - 85.1 MPa **≥ 50 MPa**	Same - Passed ISO 20795-2 requirements
Flexural Modulus (ISO 20795-1)	2,339 MPa **≥ 2,000 MPa**	2,383 MPa **≥ 2,000 MPa**	N/A	Same - Passed ISO 20795-1 requirements
Flexural Modulus (ISO 20795-2)	2,339 MPa **≥ 1,500 MPa**	N/A	2050-2130 MPa **≥ 1,500 MPa**	Same - Passed ISO 20795-2 requirements
Water Sorption (ISO 20795-1)	24.3 µg/mm^3 **≤ 32 µg/mm^3**	28 µg/mm^3 **≤ 32 µg/mm^3**	N/A	Same - Passed ISO 20795-1 requirements
Water Sorption (ISO 20795-2)	24.3 µg/mm^3 **≤ 32 µg/mm^3**	N/A	30- 32 µg/mm^3 **≤ 32 µg/mm^3**	Same - Passed ISO 20795-2 requirements
Water Solubility (ISO 20795-1)	1.1 µg/mm^3 **≤ 1.6 µg/mm^3**	0.1 µg/mm^3 **≤ 1.6 µg/mm^3**	N/A	Same - Passed ISO 20795-1 requirements
Water Solubility (ISO 20795-2)	1.1 µg/mm^3 **≤ 5 µg/mm^3**	N/A	0.5 µg/ mm^3 **≤ 5 µg/mm^3**	Same - Passed ISO 20795-2 requirements

Element	Harvest Printable Resin (Proposed Device)	NextDent Denture/ E-Denture (Primary Predicate)	E-Guard (Secondary Predicate)	Comparison
Residual Monomer	None, no methyl methacrylate (MMA) monomers used for production.	≤ 0.1 % (w/w) **≤ 2.2% (w/w)**	Unknown	Proposed device eliminates chances of residual Methyl methacrylate (MMA) monomers and associated biocompatibility issues by not utilizing MMA monomers during production.

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for the **Harvest Printable Resin** was conducted in accordance with ISO 7405:2018 *Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, Annex A*, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The biocompatibility testing included the following tests:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous Reactivity

The biocompatibility testing conducted demonstrates adequate biocompatibility for the **Harvest Printable Resin**.

ISO 20795-1 & -2 Testing

Testing according to ISO 20795-1:2013 *Dentistry - Base polymers, Part 1: Denture base polymers* and ISO 20795-2:2013 *Dentistry - Base polymers, Part 2: Orthodontic base polymers* was performed on the **Harvest Printable Resin** and as compared to the predicate devices, it is substantially equivalent to the devices and met the physical/mechanical properties of the standard.

Clinical Studies

No human clinical testing was conducted to support substantial equivalence.

8. Conclusion as to Substantial Equivalence

The similarities in chemical composition, function and intended use of the **Harvest Printable Resin** with the legally marketed predicate devices, NextDent Denture/E-Denture (K162572) and E-Guard (K201173) support substantial equivalence.