August 16, 2023

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

Re: K231389
Trade/Device Name: Harvest Dental HD Gum Strip
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI, EBF
Dated: May 20, 2023
Received: July 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,

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231389

Device Name

Harvest Dental HD Gum Strip

Indications for Use *(Describe)*

Harvest Dental HD Gum Strip is indicated for adding texture, form and color to the gingival area of a dental prosthesis which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate (PMMA), metals and ceramics (zirconia).

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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510(k) Summary **K231389**

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: July 25, 2023

2. Device:

Name of Device:	Harvest Dental HD Gum Strip
Common Name:	Composite resin for gingival area of dental prosthesis
Classification Name:	Tooth Shade Resin Material, per 21 CFR 872.3690 Denture, Relining, Repairing, Rebasing Resin, per 21 CFR 872.3760
Device Class:	II
Product Code:	EBF EBI

3. Predicate Device:

Primary Predicate: *Gradia Gum*, GC America, Inc., K033808, Product Code EBF & EBI

4. Device Description

Harvest Dental HD Gum Strip is a bondable, light-cured composite for adding texture and color to the gingival area of a dental prosthesis which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate (PMMA), metals and ceramics (zirconia). It is provided in a textured, malleable strip meant to be applied to a dentine/bone-like substructure. The strip is an alternative to the method of using a shaded composite paste to manually build-up and model visible gingival surfaces to look similar to natural gingival tissues. The **Harvest Dental HD Gum Strip** includes features such as gingival veins formed into its surface as well as being available in various shades of coloration. The strip can be easily cut, applied to the gingival surface of the restoration, then trimmed and finished with appropriate features such as gingival line and interdental papilla. Gum Strip Modifiers (paste versions of the same composite) are available in various shades and used for additional surface features and gingival repairs, and Liquid Modifiers (stains, which are a low-viscosity color-concentrated form of the same composite) are available in several shades and used for enhanced coloration resembling the natural gingiva. The **Harvest Dental HD Gum Strip** is bonded to the dental prosthesis

utilizing a bonding adhesive provided with the strip and modifiers and, after any final detailing and coloring, is to be cured utilizing a typical light-curing device.

The **Harvest Dental HD Gum Strip** is to be used by dental lab technicians and approved by licensed dental practitioners before being provided to the patient.

5. Statement of Intended Use:

Harvest Dental HD Gum Strip is indicated for adding texture, form and color to the gingival area of a dental prosthesis, which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate (PMMA), metals and ceramics (zirconia).

6. Summary of Technological Characteristics with the Predicate Device

The technological characteristics of the subject **Harvest Dental HD Gum Strip** are similar to the predicate device, Gradia Gum (K033808). There are no substantial technical or functional differences between **Harvest Dental HD Gum Strip** and the predicate device in terms of chemical composition, function and intended use. Both are composite resins used to reproduce the gingival area (gum) on dental prostheses. See Table 1 below for technological characteristics and comparisons of the composite resin for the gingival area of dental prostheses.

Table 1: Comparison of Subject and Predicate Devices

Element	Harvest Dental HD Gum Strip (Proposed Device)	Gradia Gum (Primary Predicate)	Comparison
Manufacturer	Harvest Dental Products, LLC	GC America, Inc.	N/A
510(k)	K231389	K033808	N/A
Target Users	Certified Dental Professionals and Technicians	Certified Dental Professionals and Technicians	Same
Common Name	Composite resin for gingival area of dental prostheses	Composite resin for gingival area of dental prostheses	Same
Device Description	**Harvest Dental HD Gum Strip** is a bondable, light-cured composite for adding texture and color to the gingival area of a dental prosthesis which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate	Gradia Gum is a light-cured composite resin used for the reproduction of gingival tissues by means of basic or multiple layering techniques. The material is applied using a build-up technique, color adjusted using modifiers and textured.	Similar - **Harvest Dental HD Gum Strip** is provided in a strip form rather than a paste form for ease of application and consistent thickness.

Element	Harvest Dental HD Gum Strip (Proposed Device)	Gradia Gum (Primary Predicate)	Comparison
	(PMMA), metals and ceramics (zirconia). It is provided in a textured, malleable strip meant to be applied to a dentine/bone-like substructure. The strip is an alternative to the method of using a shaded composite paste to manually build-up and model visible gingival surfaces to look similar to natural gingival tissues. The **Harvest Dental HD Gum Strip** includes features such as gingival veins formed into its surface as well as being available in various shades of coloration. The strip can be easily cut, applied to the gingival surface of the restoration, then trimmed and finished with appropriate features such as gingival line and interdental papilla. Gum Strip Modifiers (paste versions of the same composite) are available in various shades and used for additional surface features and gingival repairs, and Liquid Modifiers (stains, which are a low-viscosity color-concentrated form of the same composite) are available in several shades and used for enhanced coloration resembling the natural gingiva. The **Harvest Dental HD Gum Strip** is bonded to the dental prosthesis utilizing a		

Element	Harvest Dental HD Gum Strip (Proposed Device)	Gradia Gum (Primary Predicate)	Comparison
	bonding adhesive provided with the strip and modifiers and, after any final detailing and coloring, is to be cured utilizing a typical light-curing device. The **Harvest Dental HD Gum Strip** is to be used by dental lab technicians and approved by licensed dental practitioners before being provided to the patient.		
Indications For Use	**Harvest Dental HD Gum Strip** is indicated for adding texture, form and color to the gingival area of a dental prosthesis which includes crowns, bridges and full and partial prostheses. This composite strip is bondable to polymethylmethacrylate (PMMA), as well as metals and ceramics (zirconia).	Gradia Gum is a light-cured composite resin specifically used for the reproduction of the gum on crown and bridge prostheses.	Same - Indicated to reproduce the gingival area (gum) on dental prostheses.
Curing Mechanism	Light-Cure	Light-Cure	Same
Technique	Manual application	Manual application, build-up	Similar - **Harvest Dental HD Gum Strip** does not require any build-up.
Material Type	Urethane methacrylate, dimethacrylate, trimethacrylate, silica	Urethane dimethacrylate (UDMA), dimethacrylate, trimethacrylate, silica	Same
Flexural Strength (ISO 10477)	77 MPa **≥ 50 MPa**	124Mpa **≥ 50 MPa**	Same - Passed ISO 10477 requirement

Element	Harvest Dental HD Gum Strip (Proposed Device)	Gradia Gum (Primary Predicate)	Comparison
Vickers Hardness	N/A No direct masticatory forces on device	38Hv	Not defined for Subject device.
Occlusal Wear (vs bovine's enamel, after 200,000 times)	N/A No occlusal contact intended	170µ	Not defined for Subject device.
Storage Conditions	5-30°C, protect against direct sunlight	Store in a cool place away from direct sunlight	Similar

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for **Harvest Dental HD Gum Strip** 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. Oral Mucosa Irritation

The biocompatibility testing conducted demonstrates adequate biocompatibility for **Harvest Dental HD Gum Strip**.

ISO 10477 Testing

Testing according to ISO 10477:2020 *Dentistry. Polymer-based crown and bridge materials* was performed on the **Harvest Dental HD Gum Strip** since the strip is applied directly to a crown (or bridge) and becomes part of that device. As compared to the predicate device, it is substantially equivalent to the device 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, performance testing and intended use of **Harvest Dental HD Gum Strip** with the legally marketed predicate device, Gradia Gum (K033808) support substantial equivalence.