June 2, 2023

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

Re: K222961
Trade/Device Name: Harvest Conceal ZR Block Out
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 2, 2023
Received: May 2, 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)*

K222961

Device Name

Harvest Conceal ZR Block Out

Indications for Use *(Describe)*

Harvest Conceal ZR Block Out is indicated for burn-in zirconia shading. The applied liquid is sintered with the zirconia to adjust the restoration to match the natural color of the patient's teeth. The material is intended for professional dental work only.

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 **K222961**

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: May 2, 2023

2. Device:

Name of Device: Harvest Conceal ZR Block Out
Common Name: Liquid Stain for Dental Zirconia Restorations
Classification Name: Porcelain Powder for Clinical Use, per 21 CFR 872.6660
Device Class: II
Product Code: EIH

3. Predicate Device:

Primary Predicate: *DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid,* DMAX Co, Ltd., K173769, Product Code EIH

4. Device Description

Harvest Conceal ZR Block Out is a water-based opacifying solution available in 5 shades, white, A1, B1, C1 and D2, for use with a translucent zirconia core. It is indicated for burn-in zirconia shading. The applied liquid is sintered with the zirconia to adjust the restoration to match the natural color of the patient's teeth. Fabrication using the **Harvest Conceal ZR Block Out** requires an appropriate drying oven and sintering furnace.

5. Statement of Intended Use:

Harvest Conceal ZR Block Out is indicated for burn-in zirconia shading. The applied liquid is sintered with the zirconia to adjust the restoration to match the natural color of the patient's teeth. The material is intended for professional dental work only.

6. Summary of Technological Characteristics with the Predicate Device

The technological characteristics of the subject **Harvest Conceal ZR Block Out** is similar to the predicate device, DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid (K173769). There are no substantial technical or functional differences between **Harvest Conceal ZR Block Out** and the predicate device in terms of

chemical composition, function and intended use. Both are a water-based solutions used to shade/mask substructures when used with zirconia restorations. See Table 1 below for technological characteristics and comparisons of the liquid stain for dental zirconia restorations.

Table 1: Comparison of Subject and Predicate Devices

Element	Harvest Conceal ZR Block Out (Proposed Device)	DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid (Primary Predicate)	Comparison
Manufacturer	Harvest Dental Products, LLC	DMAX Co, Ltd.	N/A
510(k)	K222961	K173769	N/A
Target Users	Certified Dental Professionals and Technicians	Certified Dental Professionals and Technicians	Same
Common Name	Liquid Stain for Dental Zirconia Restorations	Liquid Stain for Dental Zirconia Prosthesis	Same
Device Description	**Harvest Conceal ZR Block Out** is a water-based solution available in 5 shades, white, A1, B1, C1 and D2, for use with a translucent zirconia core. It is indicated for burn-in zirconia shading. The applied liquid is sintered with the zirconia to adjust the restoration to match the natural color of the patient's teeth. Fabrication using the **Harvest Conceal ZR Block Out** requires an appropriate drying oven and sintering furnace.	DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid is a water-based solution used for the individual staining of dental zirconia frameworks and restorations prior to the final sintering. It enables trained dental technicians to adjust the restoration to match the natural color of the patient's teeth.	Same
Indications For Use	**Harvest Conceal ZR Block Out** is indicated for burn-in zirconia shading. The applied liquid is sintered with the zirconia to adjust the restoration to match the natural color of the patient's teeth. The material is intended for	DMAX coloring liquid, Chang's liquid, Confident coloring liquid, and CAMeleon coloring liquid can be used as an accessory to zirconia dioxide dental restorative material to provide individual tooth (or teeth)	Same - Indicated for shading the zirconia restorations to match the natural color of the patient's teeth.

Element	Harvest Conceal ZR Block Out (Proposed Device)	DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid (Primary Predicate)	Comparison
	professional dental work only.	shading. It is intended to be used solely by certified dental technicians for the fabrication of zirconia dioxide restorations for individual dental patients.	
Principles of Operations	Manual brushing method to zirconia framework, followed by drying and sintering processes.	Manual brushing or immersion method to zirconia framework, followed by drying and sintering processes.	Same
Material Type	Water-based opaque liquid, inorganic pigments (Water, Iron(hydroxide)oxides, iron Oxide, sodium silicate solution, magnesium oxide, calcium oxide, titanium dioxide)	Water-based with inorganic pigments (Water, nickel (II) chloride hexahydrate, iron (III) nitrate nonahydrate, sodium silicate solution, manganese (II) nitrate hexahydrate, erbium (III) nitrate pentahydrate, copper (II) nitrate trihydrate, chromium (III) nitrate nonahydrate)	Similar - differences in specific pigments
Boiling Point	100°C	100°C	Same
Density	1.05 g/cm^3	1.00 ~ 1.10 g/cm^3	Same
Specific Gravity	1.05	1.00 ~ 1.10	Same
Solubility in Water	100%	100%	Same
Storage Conditions	2-28°C, protect against direct sunlight	2-28°C, protect against direct sunlight	Same

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for **Harvest Conceal ZR Block Out** 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 Conceal ZR Block Out**.

Performance Testing

Bench Testing was conducted for the physical characteristics of **Harvest Conceal ZR Block Out** and as compared to the predicate device, it is substantially equivalent.

Clinical Studies

No human clinical testing was conducted to support substantial equivalence.

8. Conclusion as to Substantial Equivalence

The similarities in chemical composition, function, physical characteristics and intended use of **Harvest Conceal ZR Block Out** with the legally marketed predicate device, DMAX Coloring Liquid; Chang's Liquid; Confident Coloring Liquid; CAMeleon Coloring Liquid (K173769) support substantial equivalence.