December 6, 2021

DENTALMAX Co., Ltd.
Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K212548
Trade/Device Name: LUXEN CL Dental Liquid
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 20, 2021
Received: October 7, 2021

Dear Priscilla Chung:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212548

Device Name
LUXEN CL Dental Liquid

Indications for Use *(Describe)*

LUXEN CL Dental Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering.

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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K212548

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___Aug 4, 2021___

1. Applicant / Submitter:

DENTALMAX Co., Ltd.
50-7, Pungsesandan 2-Ro, Pungse-Myeon, Dongnam-Gu
Cheonan-Si, Chungcheongnamdo, Republic of Korea 31217

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine CA 92612
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	LUXEN CL Dental Liquid
Common Name:	Liquid Stain for Dental Zirconium Prosthesis
Classification Name:	Porcelain Powder for Clinical Use
Classification:	Class II, 21 CFR 872.6660
Classification Product Code:	EIH

4. Predicate Device:

Aadva Zr Coloring Liquid (K092020) by GC AMERICA Inc.

5. Device Description:

The subject device is water-based solution. It is 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.

The liquid has 100 shades. 100 shades are available in 10ml, 30ml, 50ml and 100ml volumes.

Luxen CL-Diluent and Luxen CL-Pontic Liquid are used to dilute the color of other products. Luxen CL-Pontic and Luxen-CL Diluent is used to dilute Base liquid and special color liquid.

6. Indications for Use:

LUXEN CL Dental Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- Shelf Life Test
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Sensitization & Irritation
- ISO 10993-11 - Oral mucosa irritation
- Other bench testing - Appearance, Volume, Packaging, Color Stability, Extraction

8. Substantial Equivalence

The subject device is compared to the predicate device, Aadva Zr Coloring Liquid (K092020), in the table below.

	Subject device	Predicate device
Device Name	LUXEN CL Dental Liquid	Aadva Zr Coloring Liquid
510(k)	-	K092020
Product Code	EIH	EIH
Manufacturer	DENTALMAX Co., Ltd.	GC AMERICA Inc.
Technology	Water-based with inorganic pigments	Water-based with inorganic pigments
Indication for Use	LUXEN CL Dental Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering.	Aadva Zr Coloring Liquid is a liquid used for the complete or partial coloration of milled porcelain substructures before sintering.
Principles of Operation	Brush or immerse zirconia ceramic with coloring liquid before sintering	Brush or immerse zirconia ceramic with coloring liquid before sintering
Prescription Use	Prescription only	Prescription only

Target population	General, mostly adults	General, mostly adults
Type of Packaging	Liquid container	Liquid container
Packaging Volume(ml)	30ml, 50ml and 100ml	-
Shade	Various	Various
General Physical Form	Liquid	Liquid
Sterility	Non-Sterile	Non-Sterile

The subject device is the same as the predicate device in the indications for use, principle of operation, and device characteristics. Both devices are water-based with inorganic pigments and employs brushing or immersing method for use.
The major difference would be chemical compositions, but we have performed the biocompatibility and other performance tests and the test results support that the subject device is substantially equivalent to the predict device.

9. Conclusion:

Based on the testing results, DENTALMAX Co., Ltd. concludes that the subject device is substantially equivalent to the predicate device.