September 30, 2024

Dentalmax Co., Ltd
% Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
Contact Address

Re: K241151
Trade/Device Name: LUXEN 5G
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: [NOTE: Use date of most recent supplement]
Received: April 25, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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. Ch.E., RAC, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241151

Device Name

LUXEN 5G

Indications for Use *(Describe)*

LUXEN 5G is indicated for the production of all-ceramic inlays, multi-units bridges, onlays, and veneers without zirconium dioxide frameworks.

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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K241151 - 510(k) Summary

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 2/1/2024

1. Submitter

DENTALMAX Co., Ltd.
50-7, Pungsesandan 2-Ro, Pungse-Myeon, Dongnam-Gu
Cheonan-Si, Chungnam, South Korea, 31217

2. U.S Agent/Contact Person

Priscilla Chung
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18881 Von Karman Ave STE 160, Irvine CA 92612
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3. Device

- Trade Name: LUXEN 5G
- Common Name: Dental Frame Material for Dental Prosthesis
- Classification Name: Porcelain Powder for Clinical Use
- Product Code: EIH
- Classification regulation: 21 CFR 872.6660

4. Predicate Device:

LUXEN ZR by DENTALMAX Co., Ltd. (K171585)

5. Description:

LUXEN 5G is ceramic block used to create customized dental restorations using CAD/CAM system. LUXEN 5G block are available in three shapes (Block, Wieland, D95) and various thickness sizes. LUXEN 5G is composed of yttria-stabilized zirconia and 3~4 mol % TZP. The weight of yttria is classified in accordance with ISO 6872:2015 Type2, class 5 for 3Y-TZP Zirconia.

6. Indication for use:

LUXEN 5G is indicated for the production of all-ceramic inlays, multi-units bridges, onlays, and veneers without zirconium dioxide frameworks.

7. Basis for Substantial Equivalence

1. Comparison Chart

Characteristics	Subject Device	Predicate Device	Summary
Device Name	LUXEN 5G	LUXEN ZR	None
Manufacturer	DENTALMAX CO., LTD	DENTALMAX CO., LTD	None
510(k) Number	-	K171585	None
Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Same
Product Code	EIH	EIH	Same
Device Class	II	II	Same
Indications for Use	LUXEN 5G is indicated for the production of allceramic inlays, multi units bridges, onlays, and veneers without zirconium dioxide frameworks.	LUXEN Zr is indicated for the production of allceramic inlays, multi units bridges, onlays, and veneers without zirconium dioxide frameworks.	Same
Principles of Operation	**Zirconia oxide blank is a material for crowns and bridges fabricated by CAD/CAM milling.**	**Zirconia oxide blank is a material for crowns and bridges fabricated by CAD/CAM milling.**	Same
Chemical Composition	Zirconia Powder Zpex $ZrO_2+HfO_2+Y_2O_3$ + various color powders	Zirconia Powder Zpex $ZrO_2+HfO_2+Y_2O_3$ + various color powders	Similar
Physical Characteristics & Mechanical Properties			
Standard Conformed	ISO 6872:2015	ISO 6872:2015	Same
Classification	Type II Class 5	Type II Class 5	Same
Flexural Strength (Mpa)	>800Mpa	1038 ± 135 Mpa	Similar
Thermal expansion coefficient(20-500°C)	$11.0 \times 10^{-6} K^{-1}$	$10.7 \times 10^{-6} K^{-1}$	Similar

Coefficient of thermal expansion			
Chemical solubility(μg/㎠)	< 100 μg/cm^2	< 100 μg/cm^2	Same
Radioactivity	≤ 1.0 Bq · g^{-1}	≤ 1.0 Bq · g^{-1}	Same
Sterile	Non-sterile	Non-sterile	Same
Biocompatibility			
Standard Conformed	ISO 10993-1	ISO 10993-1	Same
Classification	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Externally communicating device in oral mucosa, enamel, and dentin; and contact duration of C-long term (>30d)	Same

2. Substantial Equivalence Discussion

The subject device has the same indications for use, principle of operation, and similar chemical compositions.
The main components (ZrO2 + Hfo2 + Y2O3) and their content are similar to the comparator device, but the content of some elements is slightly different. However, the added elements are in very small amounts (<1%). We performed the biocompatibility and performance testing and the test results support that this difference does not raise a question in safety and performance.
The devices also have similar mechanical characteristics. Although the flexural strength and thermal expansion coefficient values are slightly different but both conform ISO 6872:2016 Class 5 requirements (>800Mpa).
Based on the information submitted herein, we determined that the subject device is substantially equivalent to the predicate device.

8. Non-Clinical Testing

- Performance Tests including Visual, Dimensions, Packaging, Uniformity, Freedom from extraneous materials, Chemical Solubility, Flexural Strength, Linear Thermal Expansion, Flexural Strength in accordance with ISO 6872
- Biocompatibility tests in accordance with ISO 10993-5, 10, 11, and 23
- Pyrogen Test in accordance with USP <151>

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.