DENTALMAX Co., Ltd
Jindong Kim
President
50-7, Pungsesandan 2-ro
Pungse-myeon, Dongnam-gu, Cheonan-si
Chungcheongnam-do, 31217 Kr

October 31, 2018

Re: K171585
Trade/Device Name: LUXEN Zr, LUXEN Smile
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: September 25, 2018
Received: October 2, 2018

Dear Jindong Kim:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.10.31 08:38:16 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180718

Device Name
ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES

Indications for Use *(Describe)*
ORTHODONTIC PLASTIC BRACKETS AND ACCESSORIES are indicated for orthodontic movement of natural teeth.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

LUXEN Zr, LUXEN Smile

Date: October 29, 2018

I. SUBMITTER

DENTALMAX Co., Ltd
50-7, Pungsesandan 2-ro, Pungse-myeon, Dongnam-gu, Cheonan-si,
Chungcheongnam-do, 31217, Republic of Korea
TEL : +82-41-523-3580
FAX : +82-41-523-3581
Contact Name: Kim, Jindong
Email: jdkim@hedent.co.kr

II. DEVICE NAME

Name of Device:	LUXEN Zr, LUXEN Smile
Regulation Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use
Classification regulation:	872.6660
Regulatory Class:	2
Product Code:	EIH

III. PREDICATE DEVICE

K142987, DD Bio ZX^2, Dental Direkt of Amerika UG
K142987, DD cube X^2, Dental Direkt of Amerika UG

IV. DEVICE DESCRIPTION

LUXEN Zr and LUXEN Smile are used for custom made dental restorations using a CAD/CAM system. The LUXEN Zr and LUXEN Smile are provided in 4 different shapes – block, disk, Wieland and D-95. The LUXEN Zr is composed of 3 mol% TZP. LUXEN Smile is composed of 5 mol% TZP. The weight of yttria is classified in accordance with ISO 6872:2015 Type2, class 5 for 3Y-TZP Zirconia, and ISO 6872:2015 Type2, class 4b for 5Y-TZP Zirconia, respectively.

There are various color and thickness for LUXEN Zr and LUXEN Smile;

LUXEN Zr

- Shade

  - White, S1, S2, S3, E0, E1, E2, E3, E4, Multi-ivory

- Thickness

  - Block type: 10, 12, 14, 15, 16, 18, 20, 22, 25
  - Disk type: 10, 12, 14, 16, 18, 20, 22, 25
  - Wieland type / D95 type: 10, 12, 14, 16, 18, 20, 22, 25, 30

LUXEN Smile

- Shade

  - White, S1, S2, S3, E0, E1, E2, E3, E4, Multi-white, Multi-ivory

- Thickness

  - Block type: 16
  - Disk type: 10, 12, 14, 16, 18, 20, 22, 25
  - Wieland type / D95 type: 10, 12, 14, 16, 18, 20, 22, 25, 30

V. INDICATIONS FOR USE

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

LUXEN Smile is indicated for the production of full ceramic crowns, onlays, 3-bridges and inlay bridges (anterior and molar).

VI. COMPARISON TO PREDICATE DEVICE

LUXEN Zr

Characteristics	**Subject Device**	**Predicate Device**	**Summary**
Device Name	LUXEN Zr	DD Bio ZX^2	-
Manufacturer	DENTALMAX CO., LTD.	Dental Direkt of Amerika UG	-
510(k) Number	K171585	K142987	-

Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Both products are porcelain powder for clinical use.
Product Code	EIH	EIH	Both products are EIH.
Device Class	II	II	Both products are class II.
Indications for Use	LUXEN Zr is indicated for the production of all-ceramic inlays, multi-units bridges, onlays, and veneers without zirconium dioxide frameworks.	DD Bio Z-dental blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.	Both products are indicated for dental restorations.
Blank configuration	Block type Disk type Wieland type D-95 type	Block type Disk type Wieland type D-95 type	Both products are block, disk, wieland and D-95 types.
Thicknesses	10 mm to 25 mm	10 mm to 25 mm	Both products are 10-25mm of thickness.
Crystal Morphology	3Y-TZP	3Y-TZP	Both products are 3Y-TZP.
Color	A0, A1, A2, A3, B1, B2, B3, B4, C4, B1-B2-B3-B4 LAYER	A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4	Similar Both product are met with VITA shade guide. Shade is an option that is selected according to patient's teeth color. Application of appropriate color that matches patient's teeth tone can be possible.
Sintering temperature	LUXEN Zr ST : 1580 ℃ Others : 1500 ℃	1450 ℃	Similar The sintering temperature is not exactly same, but each product has provided the optimum temperature. LUXEN Zr is higher than predicate device, but it is confirmed that the temperature improves translucent for nature color shade.
Types, Class(ISO6872:2015)	Type II Class 5	Type II Class 5	Both products are type II Class 5.
Chemical composition(wt.%)	Zirconia Powder Zpex ZrO2+HfO2+Y2O3 : >99.8	ZrO2+HfO2+ Y2O3 : ≥99 Y2O3 : <6	Similar The raw material of

	Other oxides : <0.2 ZrO_2 : 83-92 Y_2O_3 : 4-6 HfO_2 : <5 Al_2O_3 : 0.03-0.07 SiO_2 : Max 0.02 Fe_2O_3 : 0.12-0.18 Zirconia Powder Zpex Yellow $ZrO_2+HfO_2+Y_2O_3$: >99.8 Other oxides : <0.2 ZrO_2 : 83-92 Y_2O_3 : 4-6 HfO_2 : <5 Al_2O_3 : 0.03-0.07 SiO_2 : Max 0.02 Fe_2O_3 : 0.12-0.18 Zirconia Powder Zpex Pink $ZrO_2+HfO_2+Y_2O_3$: >99.8 Other oxides : <0.2 ZrO_2 : 79-92 HfO_2 : <5 Er_2O_3 : 8-11 Al_2O_3 : 0.03-0.07 SiO_2 : Max 0.02 Fe_2O_3 : Max 0.01	Al_2O_3 : <<0.15 Other oxides : <0.15	LUXEN Zr (Zpex, Zpex Yellow, Zpex Pink / Manufacturer: Tosoh) is consisted of less amount of aluminium oxide than predicate device due to translucency. However, both products meet the requirement of ISO 13356 ($Al_2O_3 \leq 0.5\%$). Also, Zpex Yellow or Zpex Pink contain Fe_2O_3 or Er_2O_3, respectively, while predicate device contains Fe_2O_3, Er_2O_3 and MnO_2. However, both products meet the requirement of ISO 13356 (other oxide < 0.5%).
Flexural strength(MPa)	1038 ± 135	1250	Similar Flexural strength is slightly lower, but higher than required by ISO 6872 for Class 5 dental ceramics(>800 MPa).
Thermal expansion coefficient(20-500℃) **Coefficient of thermal expansion**	10.7 X $10^{-6}K^{-1}$	10 X $10^{-6}K^{-1}$	Both products are 10 X $10^{-6}K^{-1}$.
Chemical solubility($\mu g/cm^2$)	0	Not listed	-
Biocompatibility	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	ISO 10993 and ISO 7405	Both products are biocompatible.
Sterile	Non-sterile	Non-sterile	Both products are non-sterile.

LUXEN SMILE

Characteristics	Subject Device	Predicate Device	Summary
Device Name	LUXEN Smile	DD cube X^2	-
Manufacturer	DENTALMAX CO., Ltd.	Dental Direkt GmbH	-
510(k) Number	K171585	K150196	-
Classification Name	Porcelain powder for clinical use	Porcelain powder for clinical use	Both products are porcelain powder for clinical use.
Product Code	EIH	EIH	Both products are EIH.
Device Class	II	II	Both products are class II.
Indications for Use	LUXEN Smile is indicated for the production of of full ceramic crowns, onlays, 3- bridges and inlay bridges(anterior and molar).	Dental blanks made from DD cubeX2 are indicated for crowns, multi-unit bridges (up to a maximum of 3 elements) and inlay bridges. Applications include both, anterior and posterior bridges.	Both products are indicated for dental restorations.
Blank configuration	Block type Disk type Wieland type D-95 type	Disk type Wieland type	Both products are Disk and Wieland type.
Thicknesses	10 mm to 25 mm	10 mm to 25 mm	Both products are 10-25mm of thickness.
Crystal Morphology	5Y-TZP	5Y-TZP	Both products are 5Y-TZP.
Color	A0, A1, A2, A3, B1, B2, B3, B4, C4, A1-A2-B3-B4 LAYER, B1-B2-B3-B4 LAYER	A0, A1, A2, A3, A3.5, B2, C2, D3	Similar Both product are met with VITA shade guide. Shade is an option that is selected according to patient's teeth color. Application of appropriate color that matches patient's teeth tone can be possible.
Sintering temperature	1450 ℃	1450 ℃	Both products are 1450 ℃.
Types, Class(ISO6872:2015)	Type II Class 4b	Type II Class 4	The proposed device LUXEN Smile is a Type II class 4b device in accordance with ISO

			6872:2015 standard while the predicate device DD cube X^2 is a Type II class 4 (Catalog, Dental Direkt GmbH) in accordance with ISO 6872:2008 standard.
Chemical composition	Zirconia Powder Zpex Smile ZrO2+HfO2+Y2O3 : >99.8 Other oxides : <0.2 ZrO2 : 80-92 Y2O3 : 8-10 HfO2 : <5 Al2O3 : 0.04-0.06 SiO2 : Max 0.02 Fe2O3 : <0.1 Zirconia Powder Zpex Yellow ZrO2+HfO2+Y2O3 : >99.8 Other oxides : <0.2 ZrO2 : 83-92 Y2O3 : 4-6 HfO2 : <5 Al2O3 : 0.03-0.07 SiO2 : Max 0.02 Fe2O3 : 0.12-0.18 Zirconia Powder Zpex Pink ZrO2+HfO2+Y2O3 : >99.8 Other oxides : <0.2 ZrO2 : 79-92 HfO2 : <5 Er2O3 : 8-11 Al2O3 : 0.03-0.07 SiO2 : Max 0.02 Fe2O3 : Max 0.01	ZrO2+HfO2+ Y2O3 : ≥99 Y2O3 : <10 HfO2 : ca.0.2 Al2O3 : <0.1 Other oxides : ≤0.05	Similar The raw material of LUXEN Smile (Zpex Smile, Zpex Yellow, Zpex Pink / Manufacturer: Tosoh) is consisted of less amount of aluminium oxide than predicate device due to translucency. However, both products meet the requirement of ISO 13356 (Al2O3 ≤ 0.5%). Also, Zpex Yellow or Zpex Pink contain Fe2O3 or Er2O3, respectively, while predicate device contains Fe2O3, Er2O3 and MnO2. However, both products meet the requirement of ISO 13356 (other oxide < 0.5%).
Flexural strength	770 ± 66 MPa	> 750-800 MPa	Similar Flexural strength is slightly lower, but higher than required by ISO 6872 for Class 4b dental ceramics(>500 MPa).
Thermal expansion coefficient(20-500℃) Coefficient of thermal expansion	10.3 X $10^{-6}K^{-1}$	10 X $10^{-6}K^{-1}$	Both products are 10 X $10^{-6}K^{-1}$.
Chemical solubility	0 μg/㎟	15 μg/㎟	Similar The lower value of

			chemical solubility has more stable, and both results of meet the requirement of ISO 6872 for Class 4b dental ceramics(>2000 μg/㎠). Therefore, it is equivalent.
Biocompatibility	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	EN ISO 10993-1, -5	Both products are biocompatible.
Sterile	Non-sterile	Non-sterile	Both products are non-sterile.

VII. PERFORMANCE(NON-CLINICAL) TESTING

The subject devices, LUXEN Zr and LUXEN Smile, and the predicate devices, DD Bio ZX^2 and DD cube X^2 were tested for the non-clinical performance including uniformity, freedom from extraneous materials, radioactivity, chemical solubility, flexural strength and linear thermal expansion.

All of test results obtained from these tests indicated that the subject devices, LUXEN Zr and LUXEN Smile, is substantially equivalent to the predicate devices, DD Bio ZX^2 and DD cube X^2, in terms of physical properties and performance.

The biocompatibility evaluation for the subject devices, LUXEN Zr and LUXEN Smile, was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1:Evaluation and Testing’” May 1, 1995, 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 device of testing included the following tests:

Contact classification:

- External communicating devices: Dentin, Enamel, Oral mucosa
- Categorization by duration of contact: C-Permanent(＞30d)

Standard:

- ISO 10993-5:2009, Cytotoxicity(MTT),
- ISO 10993-10:2010, Oral mucous Irritation,
- ISO 10993-10:2010, Sensitization(LLNA),
- ISO 10993-11:2006, Acute systemic toxicity

The results of test indicated that the subject devices, LUXEN Zr and LUXEN Smile, are considered to be biocompatible and therefore equivalent with its predicate devices, DD Bio ZX^2 and DD cube X^2 that considered biocompatibility per ISO 10993-1 and ISO 7405.

VIII. CONCLUSIONS

The indications for use and technological characteristics of the subject devices and predicate devices are substantially equivalent.