July 14, 2022

DENKEN-HIGHDENTAL Co., Ltd.
Noriko Tanji
24-3 Kisshoin Ishiharakyomichi-cho
Minami-ku, Kyoto 601-8356
JAPAN

Re: K221429
Trade/Device Name: KDF Zirconia Disc
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: May 10, 2022
Received: May 16, 2022

Dear Noriko Tanji:

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
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)*

K221429

Device Name
KDF Zirconia Disc

Indications for Use *(Describe)*

KDF Zirconia Disc is indicated for the production of dental ceramic restorations, specifically inlays, onlays, veneers, artificial teeth, crowns and bridges, which is manufactured by CAD / CAM processing. The application includes both anterior teeth and posterior teeth areas. All blocks are processed by a dental laboratory or dental technician.

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."*

# 5. 510(k) Summary

**Date of Preparation: May 10, 2022**

**Applicant:**

DENKEN-HIGHDENTAL Co., Ltd.
24-3 Kisshoin Ishiharakyomichi-cho, Minami-ku, Kyoto, 601-8356, Japan
Contact Person: Daijiro Goto
Manager of Overseas Sales Dept.
Phone: +81 75-672-2124
Fax: +81 75-672-2125
e-mail: gotou-dai@awi.co.jp

**Contact:**

Noriko Tanji
Quality Assurance Group
DENKEN-HIGHDENTAL Co., Ltd.
24-3 Kisshoin Ishiharakyomichi-cho, Minami-ku, Kyoto, 601-8356, Japan
Phone: +81-75-672-2124
Fax:+81 75-672-2136
e-mail: tanji-nor@awi.co.jp

**Manufacturer:**

Manufactured by DENKEN-HIGHDENTAL Co., Ltd.
Address; 24-3 Kisshoin Ishiharakyomichi-cho, Minami-ku,
Kyoto, 601-8356, Japan

**Name of Device(s):**

| | |
|---|---|
| Trade Name: | KDF Zirconia Disc |
| Common Name | Dental appliance fabrication materials, ceramic |
| Regulation Name(s): | Powder, Porcelain |
| Classification Name: | Porcelain powder for clinical use |

Regulation Number: 872.6660

Regulatory Class: II

Product Code: EIH

Panel: Dental

**Predicate Device**

Primary Predicate Device:

LUXEN Zr, LUXEN Smile (K171585) by DENTALMAX Co., Ltd.

Secondary Predicate Device:

Dental Zirconia Blocks (K192262) by De Corematrix Co., Ltd.

**Device Description**

KDF Zirconia Disc is used for custom made dental restorations using a CAD/CAM system by dental professionals. The subjected device has disc shapes and various shades and thicknesses as follow.

Please refer to Appendix **7** for the list of model names and specifications for KDF Zirconia Disc.

| Shade | |
|---|---|
| Monochromatic shade | Pure |
| MT series | MT-BL1, MT-BL2, MT-BL3,<br>MT-A1, MT-A2, MT-A3, MT-A3.5, MT-A4 |
| MU series | MU-Pure, MU-BL1, MU-BL2, MU-BL3<br>MU-A1、MU-A2、MU-A3、MU-A3.5、MU-A4, |
| Size | |
| Diameter (mm) | $\phi$ 98.5 |
| Thickness (mm) | 10, 14, 16, 18, 20, 22, 25, 30, 35 |

KDF Zirconia Disc is mainly composed of zirconium oxide ($ZrO_2$) and contain other oxides as stabilizers or/and colorants. The device is two different classifications according to ISO 6872: 2015 depending on shades. MU series are classified as type II class 4 ceramic, otherwise are classified as type II class 5 ceramic.

## Indications for Use

KDF Zirconia Disc is indicated for the production of dental ceramic restorations, specifically inlays, onlays, veneers, artificial teeth, crowns and bridges, which is manufactured by CAD / CAM processing. The application includes both anterior teeth and posterior teeth areas. All blocks are processed by a dental laboratory or dental technician.

## Comparison to Predicate Device

| | Proposed Device | Primary Predicate Device | | Seccondary Predicate Device | Comparison |
|---|---|---|---|---|---|
| Device Name | KDF Zirconia Disc | LUXEN Zr | LUXEN Smile | Dental Zirconia Blocks | N/A |
| Manufacturer | DENKEN-HIGHDENTAL Co., Ltd. | DENTALMAX Co., Ltd. | DENTALMAX Co., Ltd. | De Corematrix Co., Ltd. | N/A |
| 510(k) Number | | K171585 | K171585 | K192262 | N/A |
| Classification Name | Porcelain powder for clinical use | Porcelain powder for clinical use | Porcelain powder for clinical use | Porcelain powder for clinical use | Same |
| Product Code | EIH | EIH | EIH | EIH | Same |
| Device Class | Class II | Class II | Class II | Class II | Same |
| Indications for Use | KDF Zirconia Disc is indicated for the production of dental ceramic restorations, specifically inlays, onlays, veneers, artificial teeth, crowns and bridges, which is manufactured by CAD / CAM processing. The application includes both anterior teeth and posterior teeth areas. All blocks are processed by a dental laboratory or dental technician. | LUXEN Zr is indicated for the production of all ceramic inlays, multiunits bridges, onlays, and veneers without zirconium dioxide frameworks. | LUXEN Smile is indicated for the production of of full ceramic crowns, onlays, 3-bridges and inlay bridges (anterior and molar). | Dental Zirconia Blocks are intended for use for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facing, and veneers. All Blocks are processed through dental laboratories or by dental professionals. | Similar<br><br>All products are indicated for dental restorations. |
| Shapes | Disc type | Block type | Block type | Blocks, | Same |

| | | | | | |
|---|---|---|---|---|---|
| | | Disk type<br>Wieland type<br>D-95 type | Disk type<br>Wieland type<br>D-95 type | Disc | All products have a disc type. |
| Color | **-Monochronic**<br>Pure,<br><br>**-MT series**<br>MT-BL1, MT-BL2, MT-BL3, MT-A1, MT-A2, MT-A3, MT-A3.5, MT-A4<br><br>**-MU series**<br>MU-Pure, MU-BL1, MU-BL2, MU-BL3, MU-A1, MU-A2, MU-A3, MU-A3.5, MU-A4 | A0, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4 | A0, A1, A2, A3, B1, B2, B3, B4, C4, A1-A2-B3-B4<br>LAYER, B1-B2-B3-B4 LAYER | White and Colour | The shade provided on the type and amounts of pigments contained. |
| Sintering Temperature | 1500℃ | LUXEN Zr ST:1580℃<br>Others:1500℃ | 1450℃ | 1400-1600℃ | Similar |
| Types, Class (ISO 6872:2015) | **-Pure and MT**<br>Type II Class 5<br><br>**-MU**<br>Type II Class 4 | Type II Class 5 | Type II Class 4b | Type II Class 5 | Pure and MT are classified in the same type as LUXEN Zr and Dental Zirconia Blocks.<br><br>MU is classified as class 4 ceramics, so meets the requirements of Class 4b, under which LUXEN Smile is classified. |
| Chemical Composition | $ZrO_2+Y_2O_3+HfO_2$: >98<br>$Al_2O_3$: <0.5<br>$SiO_2$: <0.05<br>Other inorganic pigments: <1 | Zirconia Powder Zpex<br>$ZrO_2+HfO_2+Y_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2<br><br>Zirconia Powder Zpex Yellow<br>$ZrO_2+HfO_2+Y_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2<br><br>Zirconia Powder Zpex Pink<br>$ZrO_2+HfO_2+Er_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2 | Zirconia Powder Zpex Smile<br>$ZrO_2+HfO_2+Y_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2<br><br>Zirconia Powder Zpex Yellow<br>$ZrO_2+HfO_2+Y_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2<br><br>Zirconia Powder Zpex Pink<br>$ZrO_2+HfO_2+Er_2O_3$ :>99.8<br>Other oxides ($Al_2O_3$, $SiO_2$, $Fe_2O_3$): <0.2 | White zirconia<br>$ZrO_2+HfO_2+Y_2O_3$ : ≥99.0<br>$Al_2O_3$: ≤0.5<br>Other oxide: ≤0.5<br><br>Colour Zirconia<br>$ZrO_2+HfO_2+Y_2O_3$ ≥98.0<br>$Fe_2O_3$: <0.3<br>$Pr_2O_3$: <0.2<br>$Er_2O_3$: <1<br>Other oxide: ≤0.5 | Similar.<br><br>All products contain $ZrO_2$, $Y_2O_3$ and $HfO_2$ as the main component and small amount of other oxide. Although there are differences in pigment composition and content, they are very small amounts and do not affect performance and safety. |
| Flexural Strength | **-Pure and MT**<br>≧800 MPa | 1038±135 MPa | 770 ±66 MPa | >800 MPa | Flexural strength is higher than required |

| | | | | | |
|---|---|---|---|---|---|
| | **-MU**<br>≧500 MPa | | | | by ISO 6872 for type II class 5 or class 4 ceramics |
| Thermal Expansion Coefficient | $10.7\times10^{-6}$ $K^{-1}$ | $10.7\times10^{-6}$ $K^{-1}$ | $10.3\times10^{-6}$ $K^{-1}$ | Unknown | Same with LUXEN Zr. |
| Chemical Solubility | <100 μg/cm$^2$ | 0 μg/cm$^2$ | 0 μg/cm$^2$ | <100 μg/cm$^2$ | Chemical solubility of all products conforms to ISO 6872 for type II class 5 or class 4 dental ceramics. |
| Biocompatibility | ISO10993-1 and ISO 7405 | Device is biocompatible when used as directed by dental professionals per ISO 10993-1. | Device is biocompatible when used as directed by dental professionals per ISO 10993-1. | Comply with ISO 10993-1:2018, FDA Guidance | All products are biocompatible. |
| Sterile | Non-sterile | Non-sterile | Non-sterile | Non-sterile | Same |

## Performance (Non-Clinical) Testing

Non-clinical testing data are submitted to demonstrate substantial equivalence following FDA recognized standards:

- ISO 6872:2015, Dentistry - Ceramic materials
- ISO 7405:2018, Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

The biocompatibility studies were performed in accordance with ISO 10993 series.

### a) Performance Testing

Performance testing of the KDF Zirconia Disc was performed in accordance with ISO 6872:2015. As shown in the table below, all test results indicate that the devices conform to the requirements of the standard and falls under Type II Class 5 ceramic or Class4 ceramic as with the predicates.

Therefore, it was concluded that KDF Zirconia Disc has substantially equivalent physical properties and performance to the predicate devices.

| Test Performed | Acceptance Criteria | Results | Judgment |
|---|---|---|---|
| Uniformity and Freedom from extraneous materials | No pigment unbalance and foreign materials shall be found on any of the top, bottom, or side surfaces of the disc when visual inspection is made. | No pigment unbalance and foreign material was identified. | Passed. |
| Activity Concentration | <1.0 Bq/g of $^{238}$ U | The radioactivity concentration ($^{238}$U) of all samples was less than 1.0 Bq/g. | Passed. |
| Flexural Strength | MT series: ≧800 MPa<br>MU series: ≧500 MPa | The flexural strength of MT series with fully sintering were all greater than 800 MPa; similarly for MU series, all test articles showed greater than 500 MPa. | Passed. |
| Chemical Solubility | < 100 μg/cm$^2$ | The chemical solubilities of all fully sintered test articles were all less than 100 μg/cm$^2$. | Passed. |
| Coefficient of Thermal Expansion | (10.7±0.5) ×10$^{-6}$ K$^{-1}$ | The coefficients of thermal expansion for all fully sintered test articles were all within the range of (10.7±0.5) ×10$^{-6}$ K$^{-1}$. | Passed. |
| Shrinkage Factor | MT series:<br>1.217~1.226±0.002<br>MU series:<br>1.225~1.235±0.002 | Passed.<br><br>The shrinkage factor of MT and MU with fully sintering showed 1.217~1.226±0.002 and 1.225~1.235±0.002, respectively. | Passed. |

**b) Biocompatibility**

The biocompatibility risk assessment of KDF Zirconia Disc was performed according to ISO 10993-1:2018 and ISO 7405:2018. The tests conducted in accordance with the ISO 10993 series described above showed no significant adverse effects under the conditions of the studies. Based on the results of these studies, the risk of the biocompatibility-related hazards from the use of the device is extremely low, and all biocompatibility risks of the device are determined acceptable.

Therefore, the KDF Zirconia Disc conforms to ISO 10993-1:2018 and ISO

7405:2018, indicating that the safety of the device is substantially equivalent to the predicates.

**Conclusion**

The conclusions drawn from the comparison and analysis above demonstrate that the differences between the proposed device and the predicated device are insignificant in terms of substantial equivalence. The proposed device is substantially equivalent to the predicate device.