October 10, 2024

Yilink (Tianjin) Biotechnology Co., Ltd.
℅ Jennifer Liu
Regulatory Affairs Manager
Chenhe Medical Consulting Co., Ltd
Room 113, 7th Floor, Block B, Building 1, No. A 38,
Zhongguancun Street, Haidian District
Beijing,
CHINA

Re: K242400
Trade/Device Name: Dental porcelain powder
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 13, 2024
Received: August 13, 2024

Dear Jennifer Liu:

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, 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)*

K242400

Device Name

Dental porcelain powder

Indications for Use *(Describe)*

Dental porcelain powder is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.

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:

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Office of Chief Information Officer
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*"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."*

**Attachment 14 510(k) Summary**

K242400

# 510 (k) Summary

This summary of 510(k) for the subjective device equivalence information is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

1. **Date Summary Prepared:** May 6, 2024

## 2. Contact details

2.1 Applicant information:

| | |
|---|---|
| **Name** | Yilink (Tianjin) Biotechnology Co., Ltd. |
| **Address** | No 9 Kaituo Road, Balitai Town, Jinnan District, Tianjin City, 300350, China |
| **Tel:** | 0086- 022-88522665 |
| **Contact person and title:** | Yaqiong Zhu, Management representative |
| **E-mail** | 1039001641@qq.com |

2.2 Submission Correspondent

| | |
|---|---|
| **Name** | Chenhe Medical Consulting Co., Ltd |
| **Address** | Room 113, 7th Floor, Block B, Building 1, No. A 38, Zhongguancun Street, Haidian District, Beijing, China |
| **Tel:** | 086 633 13774915658 |
| **Contact person and title:** | Jennifer Liu/Regulatory Affairs Manager |
| **E-mail** | Jennifer19862022@163.com |

## 3. Device Name

Trade name: Dental porcelain powder

Regulation name: Porcelain powder for clinical use

Common name: Dental Ceramics

Regulatory Class: II

Product Code: EIH

## 4. Predicate Device Information

| Table 1: Predicate Device Information | | | | |
|---|---|---|---|---|
| **Owner/Operator** | **Device Trade Name** | **510 (k) No.** | **Product Code** | **Predicate** |
| Liaoning Upcera Co., Ltd | Upcera Glaze Paste, Glaze Powder, and Glaze Liquid | K181167 | EIH | Primary |

This predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

## 5. Description of Device

Dental porcelain powder is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure. Dental porcelain powder is composed of silicon oxide, aluminum oxide, boron oxide, potassium oxide, sodium oxide, lithium oxide, magnesium oxide, calcium oxide, yttrium oxide, zirconium oxide, zinc oxide, strontium oxide, barium oxide, europium oxide, titanium oxide, cerium oxide, vanadium oxide, bait oxide, praseodymium oxide, and other oxides, distilled water, 1,3-butylene glycol, 1,5-pentanediol, propanetriol, diethanolamine.

The description of varies model:

The product models are categorized into pastes (PAS), powders (POW) and liquids (LIQ) depending on the form of the product. Among them, pastes are made of powders and liquids.

The products are divided into different sizes according to the capacity of the different models.

The products are divided into different shades according to the different shades of the models of pastes (PAS) and powders (POW), and into different shades according to the strength of volatility of the products of the model of liquids (LIQ).

Dental porcelain powder is used for dental restorations, such as crown, bridge, inlay, veneer, using CAD/CAM or manual milling machines. The main ingredients of the product include zirconia, yttrium oxide, hafnium oxide, alumina and other oxides. Through the digital scanning of the tooth or tooth mold, the three-dimensional data of the tooth mold is obtained. According to the data, the CAD design is carried out to design the porcelain block processing model. Then CNC machine tool was used to make CAM according to the porcelain block processing model, and the inner crown of all-porcelain denture was made by air sintering or vacuum sintering, so as to achieve the strength and aesthetic effect required by clinical

use. Finally, the inner crown of the all-porcelain denture was glazed with porcelain powder to form the combination of porcelain, and the all-porcelain denture was made.

## 6. Indications for Use

Dental porcelain powder is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure.

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## 7. Summary of Physical and Chemical Properties Tests

Test standards and methods based on ISO 6872:2015 (Dentistry - Ceramic materials). And the results from testing demonstrate that Dental porcelain powder is substantially equivalent to the predicate device.

## 8. Technological Characteristics

All components of the subject device are based upon industry well-known chemistry. The following table shows the significant technological characteristics for the subject device and indicates the following similarities and differences with the predicate device:

Table 6: Technological Characteristics Comparison Table

| | | |
|---|---|---|
| Technological Characteristics | Subject device<br>Dental porcelain powder | Primary predicate<br>Liaoning Upcera Co., Ltd<br>Glaze Paste, Glaze Powder, and Glaze Liquid<br>K181167 |
| Product code | EIH | EIH |
| Indications for Use | Dental porcelain powder is indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure. | “Glaze Paste, Glaze Powder, and Glaze Liquid” are indicated for use as a veneering material for fixed prosthesis in crowns and bridges. This device is used in prosthetic dentistry by forming a porcelain veneer on to a ceramic substructure. |

| | | |
|---|---|---|
| Composition | The powder is composed of $SiO_2$, $Al_2O_3$, $K_2O$, $Na_2O$, $Li_2O$, and color additives.<br><br>The liquid is composed of deionized water and organic solvents. | The powder is composed of $SiO_2$, $Al_2O_3$, $K_2O$, $Na_2O$, $Li_2O$, and color additives.<br><br>The liquid is composed of deionized water and organic solvents. |
| Form | Past, liquid, and powder | Past, liquid, and powder |
| Type, class of dental ceramic | Type I – Class I | Type I – Class I |
| Single use | Yes | Yes |
| Available Color | Various | Various |
| Sterile | Non-sterile | Non-sterile |
| Physical Properties | The subject device and the predicate device have substantially equivalent physical property as they all conform to the specifications set by internal final inspection and the test method equal to ISO 6872:2015. | |

## 9. Summary of Non-Clinical Testing

Bench testing was performed per ISO 6872:2015 and internal procedures to ensure that the new device, Dental porcelain powders met its specifications. Test items include uniformity, freedom from extraneous materials, mixing and compaction performance, flexural solubility, chemical solubility, radioactivity, coefficient of thermal expansion, glass transition temperature and shade and all tests were verified to meet acceptable criteria.

The formulation of new device does not contain any non-conventional chemicals compared to the legally marketed predicate device. Biocompatibility tests were performed fully following the ISO 10993 standards to verify the equivalence of the materials that are used. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity. It is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events.

## 10. Clinical Performance Data

Not applicable. Clinical performance testing has not been performed for the subject device.

## 11. Conclusions

Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the subject device has been shown to be safe and effective. Yilink (Tianjin) Biotechnology Co., Ltd. concludes that the subject device is substantially equivalent to the predicate devices described herein.