February 10, 2023

Yilink (Tianjin) Biotechnology Co., Ltd
℅ Jennifer Liu
Regulation Affairs Specialist
Chenhe Medical Consulting Co., Ltd
Room 113, 7th Floor, Block B, Building 1,
No. A 38, Street, Haidian District
Beijing, Beijing 100080
CHINA

Re: K222513
Trade/Device Name: Glass Ceramics
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: December 9, 2022
Received: December 12, 2022

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 (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 -S

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)*

K222513

Device Name
Glass Ceramics

Indications for Use *(Describe)*

Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

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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K222513

005_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:** Feb. 2, 2023

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, Engineering manager
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: Glass Ceramics

Common name: Dental Glass Ceramics

Classification name: Powder, Porcelain

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**
Aidite (Qinhuangdao) Technology Co., Ltd.	Dental Glass Ceramics Blocks	K192231	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

Glass Ceramics contains glass ceramic blocks for dental use. The main ingredients of the product include Silica: 55%~65%; Lithium oxide: 12%~25%; Alumina: 2%~12%; Potassium oxide: 2%~14%; Other oxides: 0%~10%. Through the digital scanning of teeth or tooth mold, 3D data of tooth mold can be obtained. According to this data, CAD design can be carried out to design porcelain block processing model. Then, a CNC machine tool was used to manufacture the all-porcelain denture crown by CAM according to the porcelain block processing model. After air sintering or vacuum sintering, the all-porcelain denture was made to achieve the strength and aesthetic effect required by clinical use.

6. Indications for Use

Glass Ceramics are indicated for fabricating all-ceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.

7. Summary of Physical and Chemical Properties Tests

Test standards and methods based on ISO 6872:2015 (Dentistry - Ceramic materials) and internal final inspection standard of Yilink (Tianjin) Biotechnology Co., Ltd.. And the results from testing demonstrate that Glass Ceramics 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 4: Technological Characteristics Comparison Table

<table>
<tr><td>Technological Characteristics</td><td>Subject device
Glass Ceramics</td><td>Primary predicate
Dental Glass Ceramics Blocks
K192231</td></tr>
<tr><td>Product code</td><td>EIH</td><td>EIH</td></tr>
<tr><td>Indications for Use</td><td>Glass Ceramicss are indicated for fabricating all-ceramic restorations such as crown, bridge, inlay, veneer.</td><td>Dental Glass Ceramics Blocks are indicated for fabricating all-ceramic restorations such as veneers, inlay/onlay, partial crowns, anterior crowns, posterior crowns, using the hot press technique or CAD/CAM system.</td></tr>
<tr><td>Composition</td><td>SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides</td><td>SiO_2, Li_2O, K_2O, Al_2O_3 and other oxides</td></tr>
<tr><td>Pressing at Dental lab</td><td>Hot Press (Up. Press Series)
CAD/CAM (Up.CAD Series)</td><td>Hot Press (Up. Press Series)
CAD/CAM (Up.CAD Series)</td></tr>
<tr><td>Dimension</td><td>Various</td><td>Various</td></tr>
<tr><td>Single use</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Available Color</td><td>Various</td><td>Various</td></tr>
<tr><td>Sterile</td><td>Non-sterile</td><td>Non-sterile</td></tr>
<tr><td>Physical Properties</td><td colspan="2">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.
<table>
<tr><td>Item</td><td>Testing criteria</td><td>Subject device/HT</td><td>Primary predicate/HT</td></tr>
<tr><td>Flexural strength</td><td>≥100MPa</td><td>356.7</td><td>348.9</td></tr>
<tr><td>Chemical solubility</td><td>≤100μg·cm^{-2}</td><td>25.3</td><td>28.5</td></tr>
<tr><td>Coefficient of thermal expansion</td><td>（ 11±0.5 ） ×10^{-6}K^{-1}
（0-500℃）</td><td>10.8</td><td>10.8</td></tr>
<tr><td>Glass transition temperature</td><td>HT/MT:（520±20）℃
LT:（510±20）℃</td><td>510</td><td>510</td></tr>
</table></td></tr>
</table>

9. Summary of Biocompatibility

The new device, Glass Ceramicss, is substantially equivalent to the predicate devices that have been legally marketed for decades and with no clinical adverse events. 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. The test items include Cytotoxicity, Sensitization, Irritation, Systemic Toxicity, Subchronic Toxicity and Genotoxicity.

10. Clinical Performance Data

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

11. Non-clinical Testing

Bench testing was performed per ISO 6872:2015 and internal procedure to ensure that the Glass Ceramics

met the specifications. All tests were verified to meet the acceptance criteria.

12. 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 for its intended use and the minor differences in indications for use fall within the intended use of the predicate devices affecting neither the general intended use nor substantial equivalence. Yilink (Tianjin) Biotechnology Co., Ltd. concludes that the subject device is substantially equivalent to the predicate devices described herein.