



October 3, 2024

Hangzhou Thales Medtech Co., Ltd.  
% Chen Kaimin  
RA  
Beijing Xinranyicheng Medicine & Technology Co., Ltd.  
A-1109, Langqin International Building, No.168  
Guang'anmen Outer Street, Xicheng District  
Beijing, Beijing 10053  
China

Re: K240586

Trade/Device Name: Additive Manufacturing Zirconia Customized Restoration  
Regulation Number: 21 CFR 872.3920  
Regulation Name: Porcelain Tooth  
Regulatory Class: Class II  
Product Code: ELL, EIH  
Dated: September 9, 2024  
Received: September 9, 2024

Dear Chen Kaimin:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

The logo for the U.S. Food and Drug Administration (FDA) is displayed in a light blue color. It consists of the letters 'FDA' in a bold, sans-serif font. The 'F' and 'D' are connected at the top, and the 'A' is slightly larger and positioned to the right of the 'D'.

Bobak  
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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

## Indications for Use

Submission Number (if known)

K240586

Device Name

Additive Manufacturing Zirconia Customized Restoration

Indications for Use (Describe)

Additive Manufacturing Zirconia Customized Restoration is indicated for use as the core structure of prostheses for partially edentulous patients in need of prosthetic oral reconstruction to restore chewing function and aesthetics.

The Additive Manufacturing Zirconia Customized Restoration is a premanufactured prosthetic component and is indicated for use as restorations (Crown, Bridge, Veneer, Inlay) that will be cemented to a natural or artificial tooth abutment.

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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## I. GENERAL INFORMATION

**K240586**

**This 510(k) summary of substantial equivalence information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.**

### **Applicant:**

Hangzhou Thales Medtech Co., Ltd.

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### **Contact Person:**

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**Date Prepared: October 2, 2024**

## II. DEVICE INFORMATION

Trade Name: Additive Manufacturing Zirconia Customized Restoration

Model:Additive manufacturing of zirconia porcelain crowns and bridges;

Additive manufacturing of zirconia crowns and bridges;

Additive manufacturing of zirconia porcelain veneers;

Additive manufacturing of zirconia inlays

Common Name : Porcelain tooth

Classification Name: Porcelain Tooth

Regulation Number: 21 CFR 872.3920

Regulatory Class: Class II

Product Code: ELL

Classification Panel :Dental

Type of 510(k) submission: Traditional

### **PREDICATE DEVICE INFORMATION**

Primary Predicate device :

510(K) Number:K153534

Company Name:Nobel Biocare Usa LLC

Trade Name:NobelProcera HT ML Full Contour Zirconia Crown

Common Name:Porcelain Tooth

Product Code:ELL

### **Reference Device:**

510(K) Number:K203072

Company Name:Franz Biotech Inc.

Trade Name:Franz Zirconia Dental Crown

Common Name:Porcelain Tooth

Product Code:ELL

### **III. DEVICE DESCRIPTION**

Additive Manufacturing Zirconia Customized Restoration is an individualized dental restoration (Crown,Bridge,Veneer,Inlay) made from zirconia slurry.

Additive Manufacturing Zirconia Customized Restoration is intended to be a replacement for a natural tooth.After finalizing the Additive Manufacturing Zirconia Customized Restoration in the laboratory,it is cemented or bonded onto a tooth or artificial abutment, by a clinician,to provide a natural tooth like appearance and to restore chewing functionality in the patient's mouth.

To achieve esthetic and required value and chroma of the surrounding natural teeth the Additive Manufacturing Zirconia Customized Restoration is suitable for cut-back(veneering) or stain and glaze techniques.

The design of the Additive Manufacturing Zirconia Customized Restoration is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the restoration using or supported third party CAD systems. Once the restoration is ordered, it is sent electronically to Hangzhou Thales Medtech Co., Ltd. for fabrication.

#### **IV. INDICATIONS FOR USE**

Additive Manufacturing Zirconia Customized Restoration is indicated for use as the core structure of prostheses for partially edentulous patients in need of prosthetic oral reconstruction to restore chewing function and aesthetics.

The Additive Manufacturing Zirconia Customized Restoration is a premanufactured prosthetic component and is indicated for use as restorations (Crown,Bridge,Veneer,Inlay) that will be cemented to a natural or artificial tooth abutment.

**V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE**

<b>Description</b>	<b>Our Device</b>	<b>Predicate Device</b>	<b>Reference Device</b>	<b>Remark</b>
Manufacturer	Hangzhou Thales Medtech Co., Ltd.	Nobel Biocare Usa LLC	Franz Biotech Inc.	--
510(k) Number	K240586	K153534	K203072	--
Trade Name	Additive Manufacturing Zirconia Customized Restoration	NobelProcera HT ML Full Contour Zirconia Crown	Franz Zirconia Dental Crown	--
Indication for Use	<p>Additive Manufacturing Zirconia Customized Restoration is indicated for use as the core structure of prostheses for partially edentulous patients in need of prosthetic oral reconstruction to restore chewing function and aesthetics.</p> <p>The Additive Manufacturing Zirconia Customized Restoration is a premanufactured prosthetic component and is indicated for use as restorations (Crown,Bridge,Veneer,Inlay)</p>	<p>NobelProcera HT ML FCZ Crown is indicated for use as core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function.</p> <p>NobelProcera HT ML FCZ Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.</p>	<p>Franz Zirconia Dental Crown is indicated for use as main structure of an artificial dental prosthesis for partially edentulous patients which require prosthetic oral reconstruction to restore chewing function.</p> <p>Franz Zirconia Dental Crown is indicated for use as single crown that will be cemented to an artificial or natural tooth abutment.</p>	SE

	that will be cemented to a natural or artificial tooth abutment.			
Number of units	Crown Bridge Veneer Inlay	Individual crown	Individual crown	The number of units of restorations are different, but the K153534 and subject device are used in a similar anatomical location for a similar physiological purpose.
Material	Y-TZP Zirconium Oxide	Y-TZP Zirconium Oxide (Katana Zirconia K143439) KATANA Zirconia is used for the fabrication of the all-ceramic restorations (frameworks, FCZ crowns, FCZ bridges, inlays, onlays and veneers.)	Y-TZP Zirconium Oxide	SE
Minimum Thickness	0.3mm	0.4mm (Anterior) 0.7mm (Pre-molar and Molar)	0.4mm (Anterior) 0.7mm (Pre-molar and Molar)	SE
Biaxial Flexural Strength (MPa)(sintered)	Means±(SD)	Means±(SD)	Means±(SD)	SE
	1280(46) (meeting ISO 6872 requirements)	1092(112) (meeting ISO 6872 requirements)	1061 (meeting ISO 6872 requirements)	

Chemical Solubility ( $\mu\text{g}/\text{cm}^2$ )	<100 (meeting ISO 6872 requirements)	<25 (meeting ISO 6872 requirements)	<25 (meeting ISO 6872 requirements)	SE
Fracture Toughness ( $\text{MPa} \cdot \sqrt{m}$ )	9.24(Z-axis) 8.86(X-axis)	Unknow	6.44	SE
Thermal Expansion ( $\mu\text{m}/\text{m}^\circ\text{C}$ )	10.80	10.80	9.95	SE
Single Use	YES	YES	YES	SE
Non-sterile	YES	YES	YES	SE
Production type	3D printing(Additive Manufacturing; AM)	Nobel Biocare in-house CAM	Franz biotech in-house 3Dprinting (Additive Manufacturing; AM)	A minor technological differences between the predicate device and subject device was made by 3D print process, the predicate device was made by CNC.

## VI. PERFORMANCE DATA

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intended use. The following tests were performed on the device.

- ISO 6872 Fourth edition 2015-06-01 [including AMENDMENT 1 2018-04] Dentistry - Ceramic materials
- ISO 9693 Third edition 2019-10 Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems
- ISO 22112 Second edition 2017-08 Dentistry - Artificial teeth for dental prostheses

## VII. Biocompatibility testing

The biocompatibility evaluation and testing of the Additive Manufacturing Zirconia Customized Restoration was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- ISO 10993-1:2018(en) Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2014, Biological evaluation of medical device-Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-5:2009, Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical device-Part 10: Tests for irritation and skin sensitization.
- ISO 10993-11:2017, Biological evaluation of medical device-Part 11: Tests for systemic toxicity.
- ISO 10993-12:2012, Biological evaluation of medical device-Part 12: Sample preparation and reference materials.

Biocompatibility testing of the subject device:

No.	Standard	Test Item
1	ISO 10993-5:2009	Cytotoxicity

2	ISO 10993-10:2010	Sensitization
3	ISO 10993-10:2010	Irritation (including intracutaneous reactivity)
4	ISO 10993-11:2017	Acute systemic toxicity
5	ISO 10993-11:2017	Subchronic toxicity
6	ISO 10993-3:2014	Bacterial reverse mutation assay
7	ISO 10993-3:2014	TK Gene Mutation Test
8	ISO 10993-3:2014	Chromosome Aberration Test

### **VIII. Mechanical testing**

Additive Manufacturing Zirconia Customized Restoration's mechanical function including Radioactivity Test, Flexural strength, Linear thermal expansion coefficient test ,Fracture toughness tests and other tests which were tested and demonstrated that the design specification from design input are fulfilled. Mechanical safety tests were also conducted to demonstrate that the reliability of the device for during use no safety concern.

No animal studies or clinical testing have been required for these devices.

### **IX. Conclusion**

Based on the indications for use, technological characteristics, performance testing and comparison to the predicate device, the Additive Manufacturing Zirconia Customized Restoration has all features of predicate devices. The differences between them do not raise new question of safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.