January 19, 2022

Franz Biotech Inc.
Anita Chen
Official Applicant
5F.-3, No. 56, Ln. 258, Ruiguang Rd., Neihu Dist.
Taipei City, Taiwan 114
TAIWAN

Re: K203072
Trade/Device Name: Franz Zirconia Dental Crown
Regulation Number: 21 CFR 872.3920
Regulation Name: Porcelain Tooth
Regulatory Class: Class II
Product Code: ELL
Dated: December 22, 2021
Received: December 22, 2021

Dear Anita Chen:

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, 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)*
K203072

Device Name
Franz Zirconia Dental Crown

Indications for Use *(Describe)*
Franz Zirconia Dental Crown is indicated for use as main structure of an artificial dental prothesis for partially edentulous patients which require prosthetic oral reconstruction to restore chewing function.
Franz Zirconia Dental Crown is indicated for use as single crown that will be cemented to an artificial or natural 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.

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

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510(k) Summary K203072

510(k) Summary of Safety and Effectiveness

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

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The assigned 510(k) Number: K203072

1. Submitter

Mailing Address	Franz Biotech Inc. 4F, No. 167, Sec. 5, Minsheng E. Rd., Songshan Dist., Taipei City 105, Taiwan (R.O.C.)
Factory Address	5F.-3, No. 56, Ln. 258, Ruiguang Rd., Neihu Dist., Taipei City 114, Taiwan (R.O.C.)Establishment Registration No.: 1st submission
Contact Person	Anita Chen
Phone:	+886(0) 939-855-759
E-mail:	m9104303@gmail.com
Date Prepared	August 6, 2020

2 Device Name

Common or Usual Name	Porcelain tooth
Regulation Description	Porcelain tooth
Product Code	ELL
Device	Franz Zirconia Dental Crown
CFR Classification	CFR Part 872.3920
Device Class	II
Classification Panel	Dental

3 Predicate Device Name

510(k) number:	K153534
Trade or proprietary or model name:	NobelProcera HT ML Full Contour Zirconia Crown
Manufacturer:	NobelBiocare AB Vastra Hamngatan 1 Goteborg, SE-411 17

Sweden

4 Device Description:

Franz Zirconia Dental Crown is indicated for use as main structure of an artificial dental prothesis for partially edentulous patients which require prosthetic oral reconstruction to restore chewing function.
Franz Zirconia Dental Crown is indicated for use as single crown that will be cemented to an artificial or natural tooth abutment.

Franz Zirconia Dental Crown is intended to be a replacement for a natural tooth. After finalizing the Franz Zirconia Dental Crown in the dental 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 esthetics and required value and chroma of the surrounding natural teeth the Franz Zirconia Dental Crown is suitable for cut-back (veneering) or stain and glaze techniques.
The design of the Franz Zirconia Dental Crown is determined in a dental laboratory, hospital or dental practice by scanning, designing and ordering the crown using or supported third party CAD systems. The crown, once ordered, is sent electronically to one of Franz's centralized milling centers for fabrication.

5. Indications for Use:

Franz Zirconia Dental Crown is indicated for use as main structure of an artificial dental prothesis

for partially edentulous patients which require prosthetic oral reconstruction to restore chewing function.
Franz Zirconia Dental Crown is indicated for use as single crown that will be cemented to an artificial or natural tooth abutment.

6 Intended Use

Franz Dental Zirconia Crown is intended to be a replacement for a natural tooth.

7. Technological Characteristics and Substantial Equivalence Comparison with Predicate:

A comparison of the device features, intended use, and other information demonstrates that the Franz Dental Zirconia Crown is substantially equivalent to the predicate device as summarized in Table 1.
A minor technological differences between the predicate device and subject device was made by 3D print process, the predicate device was made by CNC. The materials, size, shape was totally the same with the predicate device. Both device was used the same technological for CAD. Although there is a slightly different technological for manufacturer process, as compared to the predicate, the performance data demonstrates the proposed device performs as safely and effectively as the predicate device. The differences raise no new question of safety and effectiveness.

Table 1

	Candidate Device	**Predicate Device**
Manufacturer	**Franz biotech Inc.**	**Nobel Biocare AB**
Device Name	**Franz Zirconia Dental Crown**	**NobelProcera HT ML Full Contour Zirconia Crown**
510(k) Number	K203072	K153534
Regulation Number	21 CFR 872.3920	21 CFR 872.3920
Regulation Name	Porcelain Tooth	Porcelain Tooth
Intended Use	Intended to be a replacement for a natural tooth.	Intended for use as an aid in prosthetic rehabilitation

Indications for Use	Franz Zirconia Dental Crown is indicated for use as main structure of an artificial dental prothesis for partially edentulous patients which require prosthetic oral reconstruction to restore chewing function. Franz Zirconia Dental Crown is indicated for use as single crown that will be cemented to an artificial or natural tooth abutment._	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. NobelProcera HT ML FCZ Crown is indicated for use as single crown that will be cemented to a natural or artificial tooth abutment.
Material	Y-TZP Zirconium Oxide	Y-TZP Zirconium Oxide (Katana Zirconia K143439)
Manufacturing Method	Franz biotech in-house 3D-printing (Additive Manufacturing; AM)	Nobel Biocare in-house CAM
Minimum Thickness	0.4mm (Anterior) 0.7mm (Pre-molar and Molar)	0.4mm (Anterior) 0.7mm (Pre-molar and Molar)
Number of units	Individual crown	Individual crown
Single Use	Yes	Yes
Number of units	Individual Crown	Individual crown
Biaxial Flexural Strength (MPa) (sintered)	Means±(SD)	Means±(SD)
	1061(90)	1092(112)
Fracture Toughness ($MPam^{0.5}$)	6.44	Unknow
Thermal Expansion (um/m℃)	9.95	10.80
Chemical Solubility in Water (ug/cm^2)	<25	<25
Sintering Temperature	1500℃	1500℃

7. Performance Testing

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

- ISO 6872 Fourth edition 2015-06-01 [including AMENDMENT 1 2018-04] Dentistry - Ceramic materials

Biocompatibility testing

The biocompatibility evaluation and testing of the Product name 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.

Mechanical testing

Franz Zirconia Dental Crown's mechanical function including Radioactivity Test, Biaxial flexural strength, Linear thermal expansion coefficient test and Fracture toughness 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.

8. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Franz Zirconia Dental Crown is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.