November 4, 2019

Besorah Dental Solutions NZ Limited
% Robin Carden
President / CEO
RAC Corporation
27134 Paseo Espada
San Juan Capistrano, California 92675

Re: K191304
Trade/Device Name: EthanZir Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: Class II
Product Code: EIH
Dated: August 5, 2019
Received: August 7, 2019

Dear Robin Carden:

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,

Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191304

Device Name
EthanZir™ Zirconia

Indications for Use *(Describe)*
EthanZir™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). EthanZir™ Zirconia blanks are intended to be milled and fully sintered by a Dental Professional or Dental Laboratory before use. Full contour monolithic crowns and bridges in anterior and posterior regions. Substructure ceramic for prostheses involving four or more units can be created.

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."

FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

K191304

510(k) Summary

for

BESORAH DENTAL SOLUTIONS NZ, LTD

EthanZir™ Zirconia

1. Submitter

BESORAH DENTAL SOLUTIONS NZ LIMITED

17/9 Chonny Crescent, Manurewa, Auckland, New Zealand, 2102

Phone: +64211268337

2. Device Name

Proprietary Name:	EthanZir™ Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use
Prior submission #:	K191304/S001

3. Predicate Devices

Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ), (K060104)

4. A. Indications for Use

EthanZir™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). EthanZir™ Zirconia blanks are intended to be milled and fully sintered by a Dental Professional or Dental Laboratory before use. Full contour monolithic crowns and bridges in anterior and posterior regions. Substructure ceramic for prostheses involving four or more units can be created.

B. Classification regulation 21 CFR 872.6660, Class II, product code EIH

5. Device Description and Function

EthanZir™ Zirconia are disc shaped dental porcelain zirconia oxide blanks that come in various sizes that are used in custom restorations by the dental laboratory. The dental laboratory will further process the blank by milling the blank based upon the anatomically rendering of the patient's teeth (done at the dental office) through "Computer Aided Drafting/ Computer Aided Machining (CAD/CAM). Once the custom rendered blank is milled the product is fully sintered and colored (if required) and fitted to the patient's teeth as dentures, crowns or bridges.

6. Physical and Performance Characteristics

Design:

CAD CAM design

Material Used:

EthanZir™ Zirconia blanks are composed of zirconia ceramics (ZrO_2) based on yttria-stabilized tetragonal zirconia (Y-TZP). The material is biocompatible according to ISO 10993-1: 2009 *"Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".*

Physical Properties:

Tabulated chart of finished product "EthanZir™ Zirconia" blanks

Sintered Density	≥ 6.09 g cm^3
Thermal Expansion coefficient (20-500°C)	10.1 µm/m °C
Bending Strength	> 900 MPa
Grain size	0.45 µm
Fracture toughness	5 $MPam^{0.5}$

Chemical Properties:

Component (chemical composition)
$ZrO_2 + HfO_2 + Y2O3 + Al_2O_3$
Y_2O_3
Al_2O_3
SiO_2
Fe2O3
Trace Elements

7. Nonclinical Testing

Besorah Dental Solutions performed a series of tests to assess whether the device is safe and effective to use. Sintered tests coupled with mechanical bench testing confirmed that the device meets specifications including established international standards and guidance documents. Density, bending strength, fracture toughness, chemical solubility and material characterization/composition of finished product was conducted to confirm that the product is safe and effective, while meeting performance goals established by standards. EthanZir™ Zirconia blanks comply with ISO 6872:2008, *"Dentistry – Ceramic materials"* and ISO 13356: 2008, "*Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)".*

8. Clinical Testing

Clinical tests have not been performed.

9. **Conclusion:** EthanZir™ Zirconia blank comparison to the predicate device Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ K060104) and is based upon similar characteristics such as: intended use, indications, contra-indications, material properties, chemical composition, processing/fabrication and testing to recognized standards and guidelines, Besorah Dental Solutions believes that EthanZir™ Zirconia blanks are substantially equivalent to these legally marketed predicate devices.