Yeti Dentalprodukte Gmbh
Thomas Biskupski
General Manager
Industriestrasse 3a
Engen, 78234 GERMANY

November 15, 2018

Re: K173971
Trade/Device Name: K2 Zirkon Blank White Classic; K2 Zirkon Blank Translucent; K2 Blank Extreme Translucent
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: August 20, 2018
Received: August 23, 2018

Dear Thomas Biskupski:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.11.15 13:23:04 -05'00'

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173971

Device Name
K2 Zircon Blank white classic, K2 Zircon Blank translucent, K2 Zircon Blank extreme translucent

Indications for Use *(Describe)*
Zircon Blanks are used for milling using digital stl-files to produce Crowns, Bridges and monolithic works. We propose the K2 Zircon Blanks for anterior and posterior restorations.

Table 1: Indication of use and maximum intermediate elements.

	Single crown		Bridges	
	Anterior	Posterior	Anterior	Posterior
K2 Zircon Blank white classic	X	X	2	2
K2 Zircon Blank translucent	X	X	2	2
K2 Zircon Blank extreme translucent	X	X	1	-

All K2 Zircon Blanks are indicated to be colored with Dip & Brush K2 CAD CAM Zircon Liquids. K2 Zircon Blanks should be not used by the general public or over-the-counter.

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.

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510(k) Summary K173971

Submitter	Yeti Dentalprodukte GmbH Industriestrasse 3 78234 Engen – Germany
Contact Person	Thomas Biskupski
Date Prepared	August 15th, 2018
K Number	K173971
Device	
Name of Device	K2 CAD CAM Zircon Blank white classic, K2 CAD CAM Zircon Blank translucent, K2 CAD CAM Zircon Blank extreme translucent
Common Name	Powder, Porcelain
Classification Name	Porcelain powder for clinical use
Regulatory Class	II
Product Code	EIH
Predicate Device	
K2 Zirconia Blank white classic:	Z-CAD HD (K072569)
Reference Devices	
K2 Zirconia Blank translucent:	Ceramill® zi (K063511)
K2 Zirconia Blank extreme translucent:	Zolid FX (K152383)

510(k) Summary

Device Description

The Yeti K2 Zircon Blanks are ceramic blanks, which are indicated for the production of dental-prosthetic restorations. The blanks named above can be machined with CAM, CAD/CAM or copy milling systems commonly used in dental medical technology and for milling using digital STL files to produce Crowns, Bridges and monolithic works made from zirconium oxide.

The Yeti Dip & Brush K2 liquids are ready for use water-based products. These liquids are specifically formulated for the colorization of K2 Zircon Blanks from Yeti Dentalprodukte GmbH.

Indications for Use

Zircon Blanks are used for milling using digital STL files to produce Crowns, Bridges and monolithic works. We propose the K2 Zircon Blanks for anterior and posterior restorations.

Table 1: Indication of use and maximum intermediate elements

	Single crown		Bridges	
	Anterior	**Posterior**	**Anterior**	**Posterior**
K2 Zircon Blank white classic	X	X	2	2
K2 Zircon Blank translucent	X	X	2	2
K2 Zircon Blank extreme translucent	X	X	1	-

All K2 Zircon Blanks are indicated to be colored with Dip & Brush K2 CAD CAM Zircon Liquids. K2 Zircon Blanks should be not used by the General public or over-the-counter.

Comparison of Technological Characteristics with the predicate device

All compared characteristics: Chemical Composition and specifications are the same for the subject and the predicate devices. There are no significant deviations.

The material consists of $ZrO_2 + HfO_2 + Y_2O_3$, Y_2O_3, Al_2O_3 and other Oxides in the subject and the predicate devices.

The shapes and dimensions are also comparable for the K2 Zircon Blank white classic, translucent and extreme translucent, with they´re predicate devices.

The defined specifications for the K2 Zircon Blank white classic, translucent and extreme translucent: Bulk density, Grain Size, Flexural Bending Strength, Fracture Toughness, Hardness (Vicker´s Hardness), Coefficient of Thermal, Radioactivity (raw material) and Solubility (acetic acid) have no significant deviations to the predicate devices.

Except for the K2 Zircon Blank white classic, there was no comparable value found for the specifications translucency and Thermal conductivity.

Performance Data

Biocompatibility testing:

The biocompatibility evaluation for the K2 Zircon Blanks was conducted to several standards for cytotoxicity, haemolysis, acute systematic toxicity, irritation, sensitization, pyrogen, chromosomal abbreviation and long-term implantation. All tests were performed in accordance to ISO 10993-1.

Bench test for each raw material or product batch:

The chemical composition and several properties are tested for each raw material batch or product batch.

Shelf Life:

Shelf-life for the K2 Zircon Blanks was set at 10 years by Yeti.

510(k) Summary

Technological Characteristics:

	New Device **K2 Zircon Blank white classic**	**Predicate Device** **Z-CAD HD**
510(k) number	K173971	K072569
510(k) submitter/ holder	YETI DENTALPRODUKTE	METOXIT
Product Code	EIH	EIH
Applications	CAD / CAM fabrication	CAD / CAM Fabrication
Material $ZrO_2 + HfO_2 + Y_2O_3$	> 99.5 %	> 99.5 %
Shape	Disks	Disks
Dimensions	Various (Diameter: 95 or 98.5 mm Height: 10 to 25 mm)	Various (Diameter: 95 or 98.5 mm Height: 10 to 25 mm)
Sterility	No	No
Single Use	Yes	Yes
Sintering Parameters	1450°C – 2 hours 1500°C – 1 hour	1450°C – 2 hours 1500°C – 1 hour
Indications for use	Zircon Blanks are used for milling using digital STL-files to produce Crowns, Bridges and monolithic works. We propose the K2 Zircon Blanks for anterior and posterior restorations.	Metoxit blanks are indicated for use as a substructure for porcelain fused ceramic fixed dental restorations.

Conclusions

Based on all information shown above and all performed testing the K2 Zircon Blank white classic, K2 Zircon Blank translucent and K2 Zircon Blank extreme translucent from Yeti Dentalprodukte GmbH are substantially equivalent to the predicate and reference devices.