July 29, 2019

Digital Age Dental Lab
Tim Mckimson
International Project Manager
2110 Artesia Blvd, Ste. B-132
Redondo Beach, California 90278

Re: K190569
Trade/Device Name: Shaders ZR
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 22, 2019
Received: April 22, 2019

Dear Tim Mckimson:

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 Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K190569

Device Name
Shaders™ Zirconia

Indications for Use *(Describe)*
Shaders™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns, and bridges). Shaders™ 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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July 10, 2019

510(k) Summary

for

Digital Age Dental Laboratories

Shaders™ Zirconia

1. Submitter

Digital Age Dental Laboratories

3I A Dan Chu Street, VSIP 2, Hoa Phu Ward , Thu Dau Mot City,

Binh Duong Province, Vietnam

Phone: +84-650-3628 100

Fax: +84-650-3628 I04

Contact Person: Tim McKimson

Email: TMcKimson@fishmandentallabs.com

2. Device Name

Proprietary Name:	Shaders™ Zirconia
Common/Usual Name:	Powder, Porcelain
Classification Name:	Porcelain powder for clinical use.
Regulation Number:	21 CFR 872.6660
Regulation Name:	Porcelain Powder for Clinical Use
Regulation Class:	II
Product Code:	EIH

3. Predicate Device:

Device Trade Name: Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ)

510 (k): K062509

Common/Usual Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use.

Regulation Number: 21 CFR 872.6660

Regulation Name: Porcelain Powder for Clinical Use

Regulation Class: II

Product Code: EIH

4. Indications for Use

Shaders™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). Shaders™ 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.

5. Device Description and Function

Shaders™ Zirconia are disc shaped dental porcelain zirconia oxide blanks that come in different 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. Substantial Equivalence

A comparison of the relevant technological characteristics between the subject and primary predicate devices is provided in the table that follows:

Feature	Shaders™ Zirconia	Prismatik™ CZ	Comment
Indications for use	Shaders™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). Shaders™ 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.	The device is indicated for use by dental technicians in the construction of custom made all ceramic restorations for anterior and posterior locations.	No change

Feature	Shaders™ Zirconia	Prismatik™ CZ	Comment
Contra-Indications	There are no specific precautions, warnings or contra-indications that are required for the safe and effective use of the device by the dental professional or patient.	There are no specific precautions, warnings or contra-indications that are required for the safe and effective use of the device by the dental professional or patient.	Same
Material Composition	Zirconia Powder: ZrO_2+HfO_2 + Y2O3 HfO_2 Y_2O_3 Al_2O_3 Other oxides	Zirconia Powder: ZrO_2+HfO_2+Y_2O_3 HfO_2 Y_2O_3 Al_2O_3 Other oxides	Same
Freedom from extraneous materials per ISO 6872:2008 Section 5.2 active conc. of not more than 1.0 Bq g^{-1} of $Uranium^{238}$	<0.03	Not supplied	Passed test
Sintered Density g/cm^{-3} No req't.	6.09 g/cm^{-3}	Not supplied	No req't
Coefficient of thermal expansion (CTE)	10.1 µm/m °C	Not supplied	Both Materials are 3m% and will have the same density

Feature	Shaders™ Zirconia	Prismatik™ CZ	Comment
Fracture toughness K_{IC}	5 MPa $m^{0.5}$	5.0 MPa $m^{0.5}$	Same
Flexural strength per ISO 6872: 2008, Limit >900MPa	1103 MPa	1100MPa	Both close to 1100 mpa
Chemical solubility per ISO 6872:2008 Limit 100 µg/cm^2	18.1 µg/cm^2	Not supplied	Test passed
Biocompatibility per ISO 10993-1: Part 1 - 'Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process."	Assured through use of same materials and manufacturing methods as legally marketed predicate devices.	*"The biological safety of the device has been assured through the selection of materials similar in composition to the other products currently on the market which have demonstrated appropriate levels of biocompatibility (see supra regarding materials and labeling for the device)."*	Similiar compositions and manufacturing methods.
Blank sizes(mm)	Disc: 98.5-100mm x 10-30mm thick	Disc: 98.5 x 10-30mm thick	Same

7. Physical and Performance Characteristics

Material Used:

Shaders™ 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 "Shaders™ 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)	**Shaders™ Zirconia (percentage by wt.)**
$ZrO_2 + HfO_2 + Y2O3 + Al_2O_3$	> 99.9
Y_2O_3	5.35 – 5.95
Al_2O_3	≤0.1
SiO_2	≤0.02
Fe2O3	≤0.01
Chemical solubility	18.1 µg/cm^2

8. Nonclinical Testing

Digital Age Dental Laboratories 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. Shaders™ 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)".*

9. Clinical Testing

Clinical tests have not been performed.

10. Conclusion: Shaders™ Zirconia blank comparison to the predicate device Glidewell Prismatik™ Clinical Zirconia (Prismatik™ CZ K060104) 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, Digital Age Dental believes that Shaders™ Zirconia blanks are substantially equivalent to these legally marketed predicate devices.