July 27, 2021

1Derful, Inc
% Robin Carden
Consultant
RAC Dental Technologies
27134 Paseo Espada, B201
San Juan Capistrano, California 92675

Re: K210884
Trade/Device Name: 1Derful HS, 1Derful HT
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 30, 2021
Received: May 6, 2021

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,

Michael E. Adjodha, M.ChE.
Assistant Director
Restorative and Surgical Dental Devices Team
DHT 1B: 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)*
K210884

Device Name
1DERFUL™ HS & 1DERFUL™ HT Zirconia

Indications for Use *(Describe)*
1Derful™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges) in the anterior/ posterior applications and not used solely as an implant. 1Derful™ Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use.

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
K210884

1. Submitter

1DERFUL, INC

Dr. Mohamad Alkassab

38345 Donigan Road, Brookshire, TX 77423

Phone: 346 331-9811

2. Device Name

Proprietary Name: 1DERFUL™ HS & 1DERFUL™ HT Zirconia
Common/Usual Name: Powder, Porcelain
Classification Name: Porcelain powder for clinical use

3. Predicate Device

NexxZr™ S / NexxZr™T - K130991

4. Indications for Use

1Derful™ Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges) in the anterior/ posterior applications and not used solely as an implant. 1Derful™ Zirconia blanks are intended to be milled and fully sintered by Dental Professional or Dental Laboratory before use.

5. Device Description and Function

1Derful™ 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.

1Derful™ Zirconia blanks are composed of zirconia ceramics (ZrO_2) based on yttria-stabilized tetragonal zirconia (Y-TZP). Shading oxide will also be used to create the need shade in the disc. These three oxide materials are Fe_2O_3, ErO_3, Co_3O_4 & Er_2O_3. All

the oxide materials have been tested as an additive for physical strengths as well as solubility and are biocompatible according to ISO 10993-1: 2009 “Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.

6. Substantial Equivalent Comparison

	1DERFUL™ HS & 1DERFUL™ HT K210884	**NexxZr™ S NexxZr™T K130991**	**Comparison**
Indications for use	1DERFUL™ HS & 1DERFUL™ HT Zirconia blanks are indicated for use in prosthetic dentistry to create porcelain (ceramic) prostheses (dentures, crowns and bridges). 1DERFUL™ HS & 1DERFUL™ HT 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.	NexxZr™ are intended for the fabrication and preparation of copings and full anatomical/full contour crowns bridge, inlays and onlays for anterior and posterior segment restorations.	Similar

	1DERFUL™ HS & 1DERFUL™ HT	NexxZS / NexxZr™T	Comparison
Material Composition % wt.	Zirconia Powder: $ZrO_2+HfO_2+Y2O3 > 99$ HfO_2: < 2 Y_2O_3: 5.2 Al_2O_3: ≤ 0.05 Other oxides: < 0.3	Zirconia Powder: $ZrO_2+HfO_2+Y_2O_3 > 99$ HfO_2: < 2 Y_2O_3: 5.2 Al_2O_3: ≤ 0.05 Other oxides: < 0.3	same
Freedom from extraneous materials per ISO 6872:2015 Section 5.2 active conc. of not more than 1.0 Bq g^{-1} of Uranium^{238}	<0.03	Not available	
Sintered Density g/cm^{-3}	6.08 g/cm^3	6.08 g/cm^3	same
Coefficient of thermal expansion (CTE)	10.1 µm/m °C	Not available	same
Fracture toughness K_{IC}	5 MPa $m^{0.5}$	5 MPa $m^{0.5}$	same
Flexural strength per ISO 6872: 2008, Limit >900MPa	>1000 MPa	>1000MPa	same

	1DERFUL™ HS & 1DERFUL™ HT	NexxZr™ S / NexxZr™T	Comparison
Chemical solubility per ISO 6872:2015 Limit 100 µg/cm^2	5.257 µg/cm^2	Not available	
Blank sizes(mm)	Disc: 98.5 mm x 10-30mm	Disc: 98.5 x 10-30mm	same
Biocompatibility	Testing Per ISO 10993	Testing Per ISO 10993	same

Physical Properties:

Tabulated chart of finished product "1Derful™ 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)	**1Derful™ 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

7. Nonclinical Testing

1Derful, Inc 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. 1Derful™ Zirconia blanks comply with ISO 6872:2015, *"Dentistry – Ceramic materials"* and ISO 13356: 2008, "*Implants for surgery, Ceramic materials based on yttria- stabilized tetragonal* 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. 1Derful™ Zirconia blanks comply with ISO 6872:2015, *"Dentistry – Ceramic materials"* and ISO 13356: 2008, "*Implants for surgery, Ceramic materials based on yttria- stabilized tetragonal zirconia (Y-TZP)".*

Standard or Test Method Used	**1DERFUL™ HS & 1DERFUL™ HT**	
Flexural Strength Test per ISO 6872:2015 Section 7.3 Requirement minimum(mean) 800 MPa for class 6 fixed prostheses, lowest value	> 1000. mpa	Pass
Freedom from extraneous materials per ISO 6872:2015 Section 5.2 active conc. of not more than 1.0 Bq g^{-1} of $Uranium^{238}$	<0.03	Pass
Chemical solubility per ISO 6872:2015 Section 7.6 Requirement of max of 100 µg cm^{-2}		Pass
Fracture Toughness per ISO 6872:2015 Section Annex A Requirement for Class 5 of 5.0 $MPa^{0.5}$ min.	5.0	Pass
Sintered density in-house calculated (d=m/v)	6.08 g/cm^3	Pass
Grain Size determined per ISO 13356:2008,	0.41 µm	Pass
Amount of monoclinic phase shall be determined using X-ray diffraction methods in accordance with ASTM F1873-98	$Zr0_2$ – Zirconium Oxide Tetragonal P42/mmc 98.5% $Zr0_2$ – Baddeleyite Monoclinic P21/a 1.5% (max)	Pass
Linear Thermal Expansion Coefficient per ISO 6872:2015	10.1 µm/m°C	Pass

Fe2O3	≤0.01	Pass
Chemical solubility	18.1 μg/cm^2	Pass

8. Clinical Testing

Clinical tests have not been performed.

9. Conclusion:

The conclusions drawn from the nonclinical and clinical tests that demonstrate that 1DERFUL™ HS & 1DERFUL™ HT Zirconia blanks are as safe, as effective, and performs as well as the legally marketed predicate device.