April 16, 2020

Dental Direkt GmbH
Patrick Berz
Regulatory Affairs Manager
Industriezentrum 106-108
Spenge, 32139 Germany

Re: K193588
Trade/Device Name: DD Contrast
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 15, 2020
Received: January 17, 2020

Dear Patrick Berz:

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,

for Srinivas “Nandu” Nandkumar, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193588

Device Name
DD Contrast

Indications for Use *(Describe)*

The DD contrast® veneering ceramics system is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.

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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Dental Direkt GmbH I Industriezentrum 106 – 108 I D-32139 Spenge

510(k) Summary

Submitter of 510(k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Person	Mr. Uwe Greitens, CEO Phone:+49 5225 86319-0 Fax: +49 5225 86319-99 u.greitens@dentaldirekt.de
Regulatory Correspondent	Mr. Patrick Berz, Manager Regulatory Affairs Phone:+49 5225 86319-0 Fax: +49 5225 86319-99 p.berz@dentaldirekt.de
Establishment Registration No.	3008347275
Date Prepared	2020/04/16
Trade Name of Device	DD contrast
Common Name	Powder, Porcelain
Classification Name	Porcelain Powder for clinical use
Product Code	EIH
Regulation Number	21 CFR 872.6660
Classification	Class II
510(k) Number	K193588

Primary Predicate Device	K111743: Jensen Industries: InSync Ceramic System (Model name: “MiYO – liquid ceramic”)
Indications for Use	The DD contrast® veneering ceramics system is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.
Device Description	DD contrast veneering ceramics are dental ceramics for the esthetic individualization of crowns and bridges made from zirconia or lithium disilicate. The DD contrast group consists of various ceramic veneering pastes (already pre-mixed) for coloring, texturing and glazing as well as liquids for adjusting the textures of the paste variants. The DD contrast products are applied to the sintered zirconium dioxide or lithium disilicate restoration and fired in a standard furnace for veneering ceramics. Due to the different consistencies, the pastes can be used to achieve thin shade and glaze layers as well as structure-building areas on the crowns. The veneering ceramics are of type I, class 1b) according to ISO 6872 (FDA Recognition Number 4-251).
Technological Characteristics	The technological characteristics of the new product are the same as those of the legally marketed device. Both products are feldspar ceramics fired onto a dental ceramic framework made of zirconium dioxide or lithium disilicate. With this veneering technique it is possible to design a crown or bridge to individual patient requirements.
Material composition	Feldspar ceramics, main components: SiO_2, Al_2O_3, B_2O_3, K_2O, Na_2O

Discussion of Tests Performed

Clinical Tests

Dental Direkt GmbH did not conduct, nor rely upon, clinical tests to determine substantial equivalence as dental ceramics that fall under FDA product code EIH have a long history of safe and effective use in the US.

Non-Clinical Tests

Non-clinical testing was performed in order to validate the product against the company's specified design requirements according to the following standards:

- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
  (FDA Recognition #4-212)

- ISO 7405, Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
  (FDA Recognition #2-258)

  The DD contrast products are proven to be biocompatible.

- ISO 6872, Dentistry - Ceramic materials
  (FDA Recognition #4-251)

Substancial Equivalence

Material

The composition of DD contrast corresponds to that of the predicate device.

Physical Properties

DD contrast has physical properties comparable to those of predicates.

Technical comparison

Feature	Predicate Device	New Device
Trade name	InSync Ceramic System	DD contrast
Model name	MiYO Esthetic System Kit	DD contrast
Indications		
Indications for Use Statement	"InSync Ceramic System": The pressable ceramic pellets are pressed onto zirconia frames by dental technicians to fabricate full ceramic crowns and the ceramic layering porcelain and liquids are used to build up the pressed ceramic to final tooth morphology and shade. The ceramic layering porcelain and liquids are also used in building ceramic crowns and bridges on titanium and titanium alloy substructures. Both applications are to provise protheses for missing / damaged teeth. "MiYO Esthetic System Kit": A Type 1, class 1b ceramic for the coloring, enhancing, and glazing of the following restoration types: Zirconia and Lithiuim Disilicate.	The DD contrast® veneering ceramics system is suitable for the esthetic individualization of monolithic or minimally reduced dental crown and bridge constructions made of zirconium dioxide or lithium disilicate.
	Comment on Indications for Use Statement: *The indication of the predicate ("InSync Ceramic System") is comparable to that of the new device, even if it is written in a very general way and includes different veneering ceramics. The relevant parts of the indication describe "layering porcelain and liquids" which are applied to a pressed ceramic veneer which has been previously pressed on a zirconium framework. Even better, however, is the comparability of the corresponding model variant ("MiYO Esthetic System Kit") resulting from this group, whose indication is identical to that of the new product.*	
Product for veneering / individualization of dental frameworks	Yes	Yes

Feature	Predicate Device	New Device
Framework material	Zirconium dioxide and lithium disilicate	Zirconium dioxide and lithium disilicate
Minimal amount of fires	2	1
For all sizes of dental frameworks	Yes	Yes
Classification acc. to ISO 6872	Type 1, class 1b	Type 1, class 1b

Feature	Predicate Device	New Device
Technological Characteristics		
Material	Feldspar ceramics	Feldspar ceramics
Form	Pastes and liquids	Pastes and liquids
Shades	Different tooth and individualization shades	Different tooth and individualization shades
Tested according to ISO 6872	Yes	Yes
Flexural strength [MPa]	≥ 50	≥ 50

Substantial Equivalence Conclusion

Dental Direkt GmbH believes that the new product DD contrast is substantially equivalent to the predicate device when used as instructed by knowledgeable and trained dental personnel. There is no change of the intended use of the new device and no difference in fundamental scientific technology. The new device is made from the same materials as the predicate device. The new device was verified in accordance with the above-mentioned FDA recognized standards.

Dental Direkt GmbH therefore believes that DD contrast is substantially equivalent to the legally marketed predicate device.