Dental Direkt GmbH
Vera Escher
Regulatory Affairs Manager International
Industriezentrum 106-108
Spenge, 32139 GERMANY

February 14, 2019

Re: K183569
Trade/Device Name: DD cube ONE ML
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: January 9, 2019
Received: January 15, 2019

Dear Vera Escher:

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: 2019.02.14 09:41:36 -05'00'

For Tina 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

Indications for Use

510(k) Number (if known): K183569

Device Name: DD cube ONE ML

Indications for Use:

DD cube ONE ML dental zirconia blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both, anterior and posterior bridges.

Prescription Use ___**X**_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) Number: K183569

Date:

510(k) Summary

Submitter of 510(k)	Dental Direkt GmbH Industriezentrum 106-108 32139 Spenge / Germany
Contact Person	Uwe Greitens, CEO Phone: +49 5225 86319-0 Fax: +49 5225 86319-99 u.greitens@dentaldirekt.de
Regulatory Correspondent:	Vera Escher, Manager Regulatory Affairs Phone: +49 5225 86319-0 Fax: +49 5225 86319-99 v.escher@dentaldirekt.de
Establishment Registration No.	3008347275
Date Prepared	2018/12/18
Trade Name of Device	DD cube ONE ML
Common Name	Powder, Porcelain
Classification Name	Porcelain Powder for clinical use
Regulation Number	21 CFR 872.6660
Classification Product Code	EIH
Panel	Dental
Classification	Class II
Predicate Device	K170885: Dental Direkt GmbH DD cube ONE (former DD cubeX² HS)

Indications for Use	DD cube ONE ML dental zirconia blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both, anterior and posterior bridges.
Device Description	DD cube ONE ML are dental milling blanks made of yttria-stabilized pre-sintered zirconium dioxide, showing a super high translucency and a high strength and fracture toughness at the same time. The ceramics are of type II (not powder), Class 5 according to DIN EN ISO 6872 (FDA Recognition Number 4-223). The material is suited ideally for crowns and bridges for both, the anterior and posterior region.
Technological Characteristics	The technological characteristics of the modified device are the same as those of the legally marketed unmodified device. Both devices are made of yttria-stabilized zirconia ceramics of high quality and with outstanding material properties. The only difference to the unmodified device is the shade. The unmodified device DD cube ONE is a white blank and the new device is a multilayer-blank. The base material is identical, and the new device only contains small amounts of coloring oxides to achieve a natural tooth shade directly after sintering. The blank has different layers: The upper part contains less coloring oxides and therefore is brighter than the medium dentine area and the darker bottom layer which contain more coloring oxides.
Comparison of Required Technology Characteristics	The following table shows a summary of the technological characteristics of DD cube ONE ML (modified product) compared to the predicate device.

Comparison of Required Technology Characteristics			
Feature	**Unmodified product**	**Modified product**	**Comment**
Trade name	DD cube ONE	DD cube ONE ML	n.a.
510(k)	K170885	this submission	n.a.
Product code	EIH	EIH	Same
Regulatory class	Class II	Class II	Same
Manufacturer	Dental Direkt GmbH	Dental Direkt GmbH	Same
Intended use	DD cube ONE dental zirconia blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both, anterior and posterior bridges.	DD cube ONE ML dental zirconia blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both, anterior and posterior bridges.	Same
Multi-unit bridges	Yes	Yes	Same.
Accessories	Yes, coloring liquids	None.	The application of coloring liquids with the new product is not reasonable, since it is already colored.
Feature	**Unmodified product**	**Modified product**	**Comment**
Chemical composition			
$ZrO_2 + HfO_2 + Y_2O3$ [wt%]	> 99.0	> 99.0	Same
Y2O3 [wt%]	< 8	< 8	Same
Al2O3 [wt%]	< 0.1	< 0.1	Same
Other oxides	< 0.05	≤ 0.8	Minor deviation due to color oxides but still below 1%
Physical characteristics [Units]			
Performance Testing	Tested according to DIN EN ISO 6872	Tested according to DIN EN ISO 6872	Same
Biocompatibility	EN ISO 10993-1, -5	EN ISO 10993-1, -5	Same

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 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:

- EN ISO 10993-1 (biological compatibility) and EN ISO 10993-5 (cytotoxicity)

DD cube ONE ML products were tested by an accredited testing laboratory with respect to biocompatibility. The laboratory certified that "the insolubility of the material is in compliance with the requirements of the standard. There is no evidence that hazardous effects will arise by release of leachable ingredients/residues". Based on the test results DD cube ONE ML was classified as eminently suitable for use in the dental applications.

- ISO 6872:2015, Dentistry - Ceramic materials (FDA Recognition # 4-223)

Requirements acc. to ISO 6872:2015:				
Requirements ISO 6872 (Clause)	**Short description**	**Required value**	**Achieved value**	**Passed / Failed**
Uniformity (Clause 5.1)	Checked by visual inspection	N/A	-	Passed
Freedom from extraneous materials (Clause 5.2.1)	Checked by visual inspection	N/A	-	Passed
Physical and chemical properties (Clause 5.2.2)	Activity concentration of uranium 238	< 1.0 Bq/g	< 0.03 Bq/g	Passed
Physical and chemical properties (Clause 4)	Flexural strength	800 MPa	1100 MPa	Passed
Physical and chemical properties (Clause 4)	Chemical solubility	< 100 µg/cm²	15.3 µg/cm²	Passed
Information supplied by the manufacturer (Clause 8.1.3)	Detailed information regarding the handling and treatment of the material	N/A	-	Passed

Substantial Equivalence Conclusion

Dental Direkt GmbH believes that DD cube ONE ML is as safe and effective as the predicate device when used as instructed by knowledgeable and trained dental personnel. There is no change of the intended use of the modified device and no difference in fundamental scientific technology. The modified device is made from the same materials as the predicate device. The new device was verified in accordance with the above FDA recognized standard. Dental Direkt GmbH therefore believes that DD cube ONE ML (modified device) is substantially equivalent to the legally marketed unmodified device.