DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 11, 2015

Dental Direkt of Amerika UG (haftungsbeschraenkt)
c/o Mr. Achim Rosner
General Manager
Pappelweg 6
32139 Spenge
GERMANY

Re: K142987
Trade/Device Name: DD Bio Z, DD Bio ZX², DD Bio ZX² color
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain powder for clinical use
Regulatory Class: II
Product Code: EIH
Dated: November 10, 2014
Received: November 13, 2014

Dear Mr. Rosner:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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): K142987

Device Name: DD Bio Z, DD Bio ZX², DD Bio ZX² color

Indications for Use:

DD Bio Z-dental blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5

510(k) Summary

510(k) Number: _____

Date: _____

510(k) Summary

Submitter of 510(k)	Dental Direkt of Amerika UG (haftungsbeschraenkt) Pappelweg 6 32139 Spenge Germany
Contact Person	Gerhard de Boer (General Manager) Tel 0049 / 5225-8 6319-0 Fax: 0049 / 5225-8 6319-99
Establishment Registration Number	3008347275
Date Prepared	November 10, 2014
Proprietary Name	DD Bio Z, DD Bio ZX², DD Bio ZX² color
Common name	Powder, Porcelain
Classification name	Porcelain powder for clinical use (21 CFR 872.6660, Product Code EIH)
Classification	Class II
Predicate Devices	K093748: Dental Direkt of Amerika UG (haftungsbeschraenkt) DD Bio Z, DD Bio Z transpa
Device Description and Intended Use	Dental milling blanks made of DD Bio Z, DD Bio ZX² or DD Bio ZX² color are semi-finished products out of yttrium-stabilized, pre-sintered zirconium dioxide for the fabrication of crown- and bridge- frameworks on commercial CAD/CAM systems or hand-operated copy-milling machines, with outstanding biocompatibility and mechanical properties. DD Bio Z-dental blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.

510(k) Number:
__K142987_____

Date:_____

Biocompatibility

All patient contacting materials used in the device are identical to those used in other FDA cleared devices, in formulation and processing, and no other chemicals have been added (e.g. plasticizers, fillers, cleaning agents, mold release agents, etc.). As usual for this type of device, the product has direct/indirect (salvia-mediated), permanent (> 30 days) contact with oral mucosa and hard tooth tissue (enamel, dentin).
According to DIN EN ISO 10993-1 biological effects which have to be considered for this type of device to prove biological safety are cytotoxicity, tissue/ mucosa irritation, sensitization, systemic toxicity, genotoxicity/ carcinogenicity and chronic toxicity.

DD Bio Z zirconia was tested by an accredited testing laboratory regarding cytotoxicity (according to DIN EN ISO 10993-5) and biological compatibility (according to DIN EN ISO 10993-1). To prove biocompatibility chemical analysis of organic and inorganic contaminants have been done. This highly sensitive chemical and biological test methods substantiated the known inert material properties and justifies the non-performance of additional toxicological tests. The material was classified as eminently suitable for use in the dental sector.

Based on the established use of the identical material in cleared devices, and on testing of the materials to the biocompatibility requirements of design standard ISO 6872:2008, additional biocompatibility testing is not considered necessary.

Clinical and Non-Clinical Testing

Dental Direkt of Amerika UG (haftungsbeschraenkt) did not conduct nor rely upon clinical tests to determine substantial equivalence. Non-clinical testing was performed in order to validate the design against the company's specified design requirements, and to assure conformance with the following voluntary design standard:
ISO 6872:2008

Risk Management

The device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program according to ISO 14971 "Medical devices – Application of risk management to medical devices".

Technological

The difference between the products of the predicate device

characteristics

K093748 and the products in the current 510(k) submission is a modification of raw materials used in the manufacture of milling blanks. Even if the material group 3Y-TZP stayed the same, the properties differ significantly and are improved. The **indication of use** for the predicate K093748 “Dental Blanks made from DD Bio Z or DD Bio Z transpa are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges” is the same as for the new product, only the product names were summarized as “DD Bio Z-dental blanks” in the new indication for use.
The modification is mainly a slightly change in the **chemical composition** by increasing the alumina content for the translucent variant DD Bio ZX2. The raw material as used for the predicate device DD Bio Z transpa had nearly no alumina contained. The missing alumina in the zirconia structure and the recommendation of a higher final sintering temperature lead to an increased grain growth and more translucency but a lowered flexural strength in comparison to DD Bio Z. Compared to DD Bio Z transpa the new DD Bio ZX² material with an increased alumina content is an improvement. DD Bio ZX² is still more translucent than the DD Bio Z material even if the sintering temperature recommendation is now the same as for DD Bio Z and the flexural strength was enhanced in comparison to the DD Bio Z transpa material. Furthermore, the utilization of colouring oxides was excluded in the first submission.

Substantial Equivalence Comparison Table

The following table shows the significant similarities and differences between the predicate products and this submission

Submitter	**Dental Direkt**	**Dental Direkt**
Device name	**DD Bio Z /** **DD Bio ZX²** (incl. pre-colored variants)	**DD Bio Z /** **DD Bio Z transpa**
510(k) No.	*this submission*	K093748
Product code	EIH	EIH
Regulatory Class	Class II	Class II

Indications for Use	DD Bio Z-dental blanks are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.		Dental Blanks made from DD Bio Z or DD Bio Z transpa are indicated for crowns, multi-unit bridges and inlay bridges. Applications include both anterior and posterior bridges.	
Chemical composition [wt%]:	DD Bio Z / DD Bio ZX²		DD Bio Z / DD Bio Z transpa	
ZrO_2 + HfO_2 + Y_2O_3	same		same	
Y_2O_3	same		same	
Al_2O_3	same	<0,15	same	<0,1
Flexural strength [MPa]	same	1200 ± 200	same	1000 ± 200

Substantial Equivalence Conclusion

Brief summary:
The material group 3Y-TZP for the products in this submission and the predicate submission stayed the same. All ceramic zirconia products incorporates the same intended use with the predicate device. The increase of Alumina content in the raw material as used for DD Bio ZX² compared to the predicate DD Bio Z transpa leads to an increase in flexural strength.
Beside this improvement the technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology. The colouring dopants in pre coloured variants have no influence on material properties They have similar labels and instructions for use (see chapter 21 “Predicates”).

Dental Direkt of Amerika UG (haftungsbeschraenkt) believes that DD Bio Z-dental blanks are as safe and effective as the predicate devices when used as instructed by knowledgeable and trained personnel, and are substantially equivalent to the legally marketed predicate devices.