K 100150

MAY 25

510(k) Summary

owner's name:	**Biodenta Swiss AG**
address:	**Tramstrasse 16** **9442 Berneck** **Switzerland**
phone:	+41 71 747 11 11
fax numbers:	+ 41 71 747 1112
name of contact person:	Mr. David Eiler
date the summary was prepared:	2010-05-19
name of the device:	**ceramics2in1**
trade or proprietary name:	**ceramics2in1**
the classification name:	powder, porcelain
	(21 CFR 872.6660; Product Code EIH)
Legally marketed device to which your firm is claiming equivalence	The following predicate device is used to show the substantial equivalence concerning the general design of the **ceramics2in1** system
company:	Dentaurum, Inc.
device:	Triceram
510(k) No.:	K011428

Indications for Use:
The dental ceramic ceramics2in1 is a low fusing dental ceramic sinter material for the production of crowns and bridges made of zirconium oxide or titanium based coping and frameworks.
The system comprises ceramic materials typical for dental ceramics: shoulder margin, opaque, opaque dentin, dentin, incisal, effect, opal, gingiva, addon correction material, stains, shades, glaze and liquids

- Veneering of titanium copings / frameworks
- Veneering of zirconium oxide based copings / frameworks

Device Description:
The **ceramics2in1** is a porcelain powder system for bonding to titanium or zirconium dental frameworks or copings. The device is used in prosthetic dentistry by heating in an oven to produce a hard prosthesis with a glass-like finish.
The system comprises ceramic materials typical for dental ceramics: shoulder margin, opaque, opaque dentin, dentin, incisal, effect, opal, gingiva, addon correction material, stains, shades, glaze and liquids

Composition:
The ceramics2in1 consists of following components: SiO_2, ZrO_2, Al_2O_3, B_2O_3, K_2O, Na_2O, SrO, CeO_2, SnO_2, ZnO, P_2O_5, CaO, Li_2O, F and pigments. Despite differences in the chemical composition to the predicated device the ceramics2in1 does not show any unacceptable toxic or allergic potential and is considered to be highly biocompatible. According to the biocompatibility evaluation the following statement is valid: Due to the current standard of knowledge the ceramics2in1 dental porcelain system does not show unacceptable health risks arising for patients, applying technicians or dentists

Physical properties:
All components forming the final veneering have been evaluated on soludablity according to ISO 6872 and bond strength and flexural strength according to ISO 6872. The results are not significantly different to the predicate device and are all within the limits of the standards.

Conclusion:
The overall composition of the system, the technological characters, physical properties and indications of the **ceramics2in1** are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 25 2010

Mr. David Eiler
Regulatory Affairs Manager
Biodenta Swiss AG
Tramstrasse 16
Berneck
Switzerland 9442

Re: K100150
Trade/Device Name: Ceramics2in1
Regulation Number: 21CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: May 7, 2010
Received: May 10, 2010

Dear Mr. Eiler:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100150

Device Name: **ceramics2in1**

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- Veneering of zirconium oxide based copings / frameworks

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mackey for MSR

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100150