K103773

MAR 16 2011

5. 510 (k) Summary

This 510(k) summary provides the basic principle for determination of substantial equivalence according to 21 CFR Part 807.92.

1. Submitter of 510(k)

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2. Device name

Trade name:	Zenoflex dimension
Common name:	Veneering ceramic
Classification name:	Porcelain powder for clinical use (21 CFR 872.6660, Product code: EIH, Class II)

3. Legally marketed equivalent device

Predicate device:	Zirox
510(k) number:	K051249

Date of Summary: 12/07/2010

K103773

510 (k) Summary

4. Description of the Device

Zenoflex dimension is a dental porcelain system that consists of about 150 different ceramic powders and it is intended to be used by professional dental technicians to manufacture all-ceramic dental appliances for the sole use of particular patients. Zenoflex dimension is recommended for veneering zirconium dioxide (ZrO_2) frameworks with a coefficient of thermal expansion [$CTE_{(25\text{-}500°C)}$] of approximately $10{,}5 \times 10^{-6} K^{-1}$.

The Zenoflex dimension ceramic offers the dental technician the possibility to chose between different kinds of layer techniques considering aesthetical and economical aspects.
The "One layer technique", which is a fast and simple procedure to manufacture ceramic restorations, considers primarily the economical aspects. For manufacturing ceramic restorations the user needed numerous types of ceramic (dentine and incisal ceramics) so far. But now less types of ceramic are necessary for manufacturing anatomical crowns or bridges and for achieving the desired dental colour.
The "Three layer techniques" enable the user to achieve a dental restoration with a more aesthetical result, because this layer technique comprises the application of at least three different types of ceramic.
With the "Professional layer technique" the dental technician can carry out an extended professional build-up to achieve a dental restoration with the most aesthetical result.

Furthermore the Zenoflex dimension ceramic enables the user to manufacture dental restorations with colours of the "VITA Toothguide Classical" as well as of the "VITA Toothguide 3D-Master".

5. Intended Use of the Device

Zenoflex dimension is a dental ceramic, which is suitable for veneering hard-sintered zirconium dioxide frameworks with a coefficient of thermal expansion (CTE 25-500°C) of approx. $10.5 \times 10^{-6} K^{-1}$.

6. Comparison with the predicate device

Zenoflex dimension is substantially equivalent to the medical device Zirox.

Zenoflex dimension as well as Zirox is dental porcelain, which is made of glass frit. Both have similar indications for use, in which they are intended to be used by professional dental technicians to veneer zirconium dioxide (ZrO_2) frameworks to manufacture dental restorations. Physical, biological and chemical properties of the device, like bending strength, coefficient of thermal expansion, biocompatibility and chemical solubility were tested according to international accepted standards, e.g. ISO 6872, ISO 7405, and meet their demands, respectively, and indicate high safety and effectiveness.
Considering these excellent material properties and the numerous similarities as well as the lack of any significant differences between both devices, it can be concluded, that Zenoflex dimension is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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GERMANY

MAR 16 2011

Re: K103773
Trade/Device Name: Zenoflex dimension
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 7, 2010
Received: December 27, 2010

Dr. Polzer:

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): K103773

Device Name: Zenoflex dimension
Indications for Use:

Zenoflex dimension is a dental ceramic, which is suitable for veneering hard-sintered zirconium dioxide frameworks with a coefficient of thermal expansion (CTE 25-500°C) of approx. 10.5 x 10^{-6} K^{-1}.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K103773