K123680

FEB 2 1 2013

510(k) Summary

owner's name:	White Peaks Dental Systems GmbH & Co. KG
address:	Langeheide 9 45239 Essen Germany
Establishment registration no.:	3009409473
Contact person:	Oliver Puckert
Phone / Fax	+49-281-206458-0 / +49-281-206458-13
Name of the device:	CopranColor
Trade or proprietary name:	CopranColor
Classification name:	Powder, Porcelain
Device classification:	2
Regulation / Product code:	21 CFR 872.6660 / EIH

Predicate device equivalence:

CopranColor equals the predicate device with respect to the indications for use and the fundamental technology, relating to the use of Zirkonium dioxide blanks, the application process (CAD/CAM technology), the biocompatibility, coloring system and other technical aspects.

Device Descripton

CopranColor is a device that may be used as an accessory to zirkonium dioxide.dental restaurations such as Copran ZR /Origin YZ.

Together with the zirconium dioxide blanks the CopranColor can be used by professional dental technicians for fabrication of all.ceramic restorations.

Indications for Use

CopranColor is intended to be used as the coloring agent for the shading of white zirconia ceramic materials that are intended to be used by professional dental technicians to fabricate all-ceramic dental restorations for the sole use of particular patients.

Comparison of Technology Characteristics

The CopranColor is a liquid including colorants that is used prior to the final sintering of the restoration enabling the user to adjust the restoration to match the natural color of the patient´s teeth.

The colouring liquid has no negative effect to the physical material properties.

This includes the variants:

- Copran Color (used for white Ziconium)
- Copran Ultra-T Color (used for ceramic blending)
- Copran Monolith Color (used for milled teeth)

Determination of Substantial Equivalence

CopranColor in combination with the zirkonia blanks has the same technological characteristics as the predicate device ZENOTEC Zr / ZENOSTAR Color Zr.

The new device has the following similarities to the previously cleared predicate device:

- Same intended use
- Same operating principles
- Same technology
- Same manufacturing process

The materials used in the new devices are all biocompatible as the predicate device.

Conclusion drawn from nonclinical / clinical test:

Based on the above and the fact that main component CopranZR is cleared for the US market since 2009 we consider the device CopranColor being safe and effective and we conclude the device is substantially equivalent to the predicate device: .ZENOTEC Zr / ZENOSTAR Color Zr.

Summary of Device Testing:

Bench testing was performed to ensure that the CopranColor met its specifications. All tests were verified to meet acceptance criteria. Biocompatibility testing was performed to verify the equivalent safety of the materials that are used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 21, 2013

Mr. Oliver Puckert
CEO
White Peakes Dental Systems GmbH & Co. KG
Langeheide 9
45239 Essen
GERMANY

Re: K123680
Trade/Device Name: CopranColor
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 13, 2012
Received: November 30, 2012

Dear Mr. Puckert:

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,

Susan Runner, DDS, MA
Mary S. Runner
2013.02.21
12:03:50 -05'00'

FOR Anthony D. Watson, B.S., M.S., M.B.A.
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): K123680

Device Name: CopranColor

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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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Susan Runner, DDS, MA

Mary S. Runner
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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