K092496

SEP 18 2009

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# 510(k) Summary

| | |
|---|---|
| owner's name: | **White Peaks Dental Systems** GmbH& Co KG |
| address: | **Langheide 9**<br>**45239 Essen**<br>**Germany** |
| phone: | +49 281 2064 5812 |
| fax numbers: | + 49 281 2064 5813 |
| name of contact person: | Mr. Oliver Puckert |
| date the summary was prepared: | 2009-07-21 |
| Establishment Registration number: | PENDING |
| name of the device: | **Copran Zr**/ Origin YZ<br>*Remark:*<br>*It is intended to market the identical device under two brand names: "Copran" and "Origin", whereas the majority of products sold to the USA will be "Origin".* |
| trade or proprietary name: | **Copran Zr**/ Origin YZ |
| the classification name: | powder, porcelain<br>(21 CFR 872.6660 Product Code EIH) |

Legally marketed device to which your firm is claiming equivalence

| | |
|---|---|
| Company: | Wieland |
| Device: | Zeno Zr |
| 510(k) No.: | K073108 |

**Indications for Use**

**Copran Zr/** Origin YZ Zirconia blanks are presintered blanks for CAD CAM or manual milling, made from biocompatible, tetragonal and polycrystalline zirconiumdioxyde. Milling blanks designed for:

- Crown frameworks in the anterior and posterior areas
- Bridge frameworks in the anterior and posterior areas
- Primary conical crowns and telescopic crowns
- Cantilevered bridges with a max. of one pontic having a premolar width
- Inlays, Onlays, Veneers

**Shapes**

The devices are sold in different shapes, figures and dimensions to match the specification of the different CAD/CAM milling machines used to generate the final restaurations.

This may be shapes like disks, cubes, bars and cylinders. (Examples see chapter 13, product labels)

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 18 2009

White Peaks Dental Systems GmbH & Company KG
C/O Mr. Stefan Preiss
Responsible Third Party Official
TUV SUD America, Incorporated
1775 Old Highway 8 NW
New Brighton, Minnesota 55112-1891

Re: K092496
Trade/Device Name: Copran Zr/Origin YZ
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical use
Regulatory Class: II
Product Code: EIH
Dated: September 11, 2009
Received: September 14, 2009

Dear Mr. Preiss:

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.

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

Susan Runner, D.D.S., M.A.
Acting 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): K092496

Device Name: **Copran Zr**/ Origin YZ

**Copran Zr**/ Origin YZ Zirconia blanks are presintered blanks for CAD CAM or manual milling, made from biocompatible, tetragonal and polycrystalline zirconiumdioxyde.

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- Inlays, Onlays, Veneers

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K092496