



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

November 5, 2014

Zirkonzahn, GmbH  
c/o Donna Marie Hartnett  
Attorney / Consultant  
Radack & Hartnett  
67 Main Street  
Silver Creek, NY 14136

Re: K132230

Trade/Device Name: ICE Zirkon Transluzent Plus  
Regulation Number: 21 CFR 872.6660  
Regulation Name: Porcelain Powder for Clinical Use  
Regulatory Class: II  
Product Code: EIH  
Dated: September 29, 2014  
Received: October 03, 2014

Dear Ms. Hartnett:

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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A faint, semi-transparent watermark of the FDA logo is visible behind the signature.

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 (rev)

510(k) Number (if known): K132230

Device Name: ICE ZIRKON TRANSLUZENT PLUS

### Indications For Use:

For the fabrication of metal free single and multiple unit crowns/bridges, inlays, onlays bonded dental restorations.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

**510(K) SUMMARY** (rev 11.3.2014)  
**Zirkon ICE Transluzent Plus**

Contact: Manfred Gasteiger, Quality Assurance  
Company: Zirkonzahn, GmbH, An der Ahr 7, 39030 Gais, Italy  
Telephone: +39 0474 066 660

Date Prepared: January 27, 2014

Trade Name: ICE Zirkon Transluzent Plus  
Classification Name: Porcelain Powder for Clinical Use (872.6660) (Class Code EIH)  
Predicate Devices: Zirkonzahn ICE - K061851, Zirkonzahn, GmbH

Device Description: ICE Zirkon Transluzent Plus is a dental porcelain system composed of zirconia based blocks which utilizes CAD/CAM technology for dental restoration fabrication.

Intended Use: For the fabrication of metal free single and multiple unit crowns/bridges, inlays, onlays bonded dental restorations

Technological Characteristics: The ICE Zirkon Transluzent Plus device represents a modification of the existing Zirkonzahn ICE device (510k No. K061851) to improve the translucency of the materials while maintaining the mechanical strength. The materials are intended to be used with the CAD/CAM Technology for fabrication of the restoration. Zirconia has been commonly used in dentistry in the CAD/CAM area for many years due to its high flexural strength and esthetics. ICE Zirkon Transluzent Plus is substantially equivalent to the predicate device regarding the indications for use, material properties, technical parameters, processing and biocompatibility.

Testing Summary: ICE Zirkon Transluzent Plus was tested according to ISO 6872:2008 and is classified as Type II Class 1a&b and 2a esthetic dental ceramic. The device has been tested for flexural strength, chemical solubility, radioactivity, glass transition temperature and CTE, and the results of such testing are substantially equivalent to the predicate devices. Slight differences do not adversely affect safety and effectiveness of ICE Zirkon Transluzent Plus compared to the predicate.

All of the components have been used in legally marketed devices. The formulations have not been changed in way that may adversely impact safety or efficacy.

The prior use of the components in legally marketed devices, the similarity in the formulations between the modified device and the marketed device, and the data provided regarding the modifications to the marketed device support the safety and effectiveness of the ICE Zirkon Transluzent Plus for the intended use.

Conclusion: The data submitted demonstrates that the subject device is substantially equivalent to the predicate device.