



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

October 9, 2014

A&D Dental Innovations, LLC
Mr. Yoonho Jun
Project Manager
9308 Evening Primrose Path
Austin, TX 78750

Re: K141659
Trade/Device Name: PRISM Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: July 16, 2014
Received: July 16, 2014

Dear Mr. Jun:

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 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>. 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,

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

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

4. Indications for Use

510(k) Number: K141659

Device Name: PRISM Zirconia

Indications for Use:

This device is a ceramic blank for fabrication of dental restoration in anterior and posterior locations. This device is used for fabricating copings, crowns, inlays, onlays, veneers and bridges.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)

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5. 510(k) Summary

1. Submitter

A & D DENTAL INNOVATIONS, L.L.C.
9308 EVENING PRIMROSE PATH
AUSTIN, TX 78750
Phone: 1-888-374-5134
Fax: 1-888-374-5134
Contact: Yoonho Jun, Project Manager
Date Prepared: July 10, 2014

2. Device Name

Trade Name: PRISM Zirconia
Common Name: Zirconia dental blank
Panel: Dental
Classification Name: 21 CFR 872.6660: Porcelain powder for clinical use
Class: Class II device
Product Code: EIH

3. Predicate Devices

Prismatik™ Clinical Zirconia (Glidewell Laboratories, K060104)

4. Device Description

The device is a strong and esthetic dental ceramic blank that is used by dental laboratories for fabrication of dental prosthetics such as copings, crowns and bridges. The device is comprised mainly of zirconium oxide powder and is used by dental CAD/CAM systems currently available in the market. The device is initially manufactured in a partially sintered state and is milled to specifications using standard CAD/CAM milling machines by dental technicians. The milled units are then sintered fully to the final state that is capable of being used in dental restoration procedures by dentists.

5. Intended Use

This device is a ceramic blank for fabrication of dental restoration in anterior and posterior locations. This device is used for fabricating copings, crowns, inlays, onlays, veneers and bridges.

6. Technical Characteristics

PRISM Zirconia is designed to be the same as or similar to the predicate device in terms of intended use, material, chemical composition, dimensions and material properties. Both the submitting and predicate devices are manufactured by colloidal casting of zirconia powder. Both devices are dental ceramic discs with a diameter of 98 mm and composed of yttrium oxide stabilized zirconium oxide which is a common chemical composition for dental zirconia blanks. Any potential discrepancy in composition is with the minor dispersing agents, which are used during the manufacturing process and are released completely during the presintering process.

7. Substantial Equivalence

Performance testing including flexural strength, thermal expansion and solubility has been performed for the submitting and predicate devices to establish substantial equivalence to the predicate device. The testing results show that our PRISM Zirconia is substantially equivalent to the predicate device in terms of effectiveness and safety.