K081850

SECTION 5 – 510(k) SUMMARY

SEP 2 5 2008

Submission Correspondent:	Emergo Group, Inc.
Address:	1705 S. Capital of Texas Hwy Suite 500 Austin, TX 78746
Phone:	(512) 327-9997
Fax:	(512) 327-9998
Contact:	Stuart R. Goldman
Submission Sponsor:	Zircar Zirconia, Inc. PO Box 287 Florida, NY 10921-0287 Tel: 845.651.3040 Fax: 845.651.0074 www.zircarzirconia.com
Date Prepared:	May 30, 2008
Trade Name :	Bisque Zirconia Blanks, Type BYZ
Common/Usual Name:	Porcelain Powder Blocks for Dental Restorations
Classification Name:	Porcelain Powder for Clinical Use
Classification Number:	872.6660
Classification Panel:	Dental Devices
CDRH Product Code:	EIH
Regulatory Class:	II
Device Description:	Zircar Zirconia Blanks, Type BYZ, are high purity, bisque fired zirconia machining blanks. The powders pressed to form these blanks are of a uniform size and well dispersed, ensuring no agglomerates. The resultant fine grained, bisque body allows intricate shapes to be machined with tight tolerances. BYZ blanks are phase stabilized

with 3 mol% yttria and therefore do not undergo the usual phase transitions associated with pure zirconia. This phase transformation "toughens" the zirconia and stops crack propagation, yielding high fracture toughness and high strength. The highest purity powders are used to make Type BYZ minimizing trace oxides. Type BYZ is 99.9 wt% ZrO_2 + $Y2O_3$ + HfO_2 + Al_2O_3. The natural zirconia minerals HfO_2, which is so similar in structure and chemical properties to zirconia, that it has no effect on product properties. A small addition of alumina minimizes hydrothermal aging.

Zircar Zirconia Blanks, Type BYZ, are dental ceramic blanks designed for the manufacturing of substructures for ceramic dental appliances. The dental appliance is machined either by CAD/CAM machining or using the copying technique. Products are either porous or dense. Porous blanks are then sintered to full density and strength. Dense blanks do not need a final heat treatment and are therefore ready for veneering immediately after machining. All appliances are for the sole use of the particular patient only. At the dental lab, a metal chuck is glued on the end of blank that holds it in the CAD/CAM machine which is used to machine the final dental restoration. At he completion of the machining steps, the dental restoration is fired (i.e., sintered) in the oven to harden the ZrO_2.

Intended Use:

Bisque Zirconia Blanks, Type BYZ
are indicated for use as a substructure for ceramic dental restorations.

All blanks are solely by or on the order of a dental professional. They are not for use by the general public or over-the-counter.

Predicate Devices:

1. Sagemax Z-Blank (K062695)
2. Vita In-Cream YZ Cubes for Cerec (K022996)

Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different

technological characteristics. But, it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

As such, it has been shown in this 510(k) submission, that the differences between the Bisque Zirconia Blanks, Type BYZ and the predicate devices do not raise any questions regarding their safety and effectiveness.

The Bisque Zirconia Blanks, Type BYZ, as designed and manufactured are as safe and effective as the predicate device and therefore are determined to be substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

Zircar Zirconia, Incorporated
C/o Mr. Stuart R. Goldman
Senior Consultant
Emergo Group, Incorporated
1705 South Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K081850
Trade/Device Name: Bisque Zirconia Blanks
Regulation Number: 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: June 11, 2008
Received: July 2, 2008

Dear Mr. Goldman:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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): K081850

Device Name:

Bisque Zirconia Blanks

Type: BYZ

Sizes:

15mmx 20mm x 15mm TK
19mm x 40mm x 15mm TK
54mm x 103mm 15mm TK
9mm x 55mm x 15mm TK
25mm x 65mm x 22mm TK
25mm x 62mm x 15mm TK
25mm x 57mm x 15mm TK

Indications for Use:

Bisque Zirconia Blanks, Type BYZ are indicated for use as a substructure for ceramic dental restorations.

All blanks are solely by or on the order of a dental professional. They are not for use by the general public or over-the-counter.

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)

Susan Runner

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

510(k) Number: K081850