K082652

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SECTION 5 – 510(k) SUMMARY

Submission Correspondent

Emergo Group, Inc.

DEC 30 2008

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Stuart R. Goldman

Submission Sponsor

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Date Prepared

June 30, 2008

Trade Name

Bittar Zirconia Blocks

Classification Name

Porcelain Powder for Clinical Use

Classification Number

872.6660

Classification Panel

Dental Devices

CDRH Product Code

EIH

Regulatory Class

Class II

Device Description

Bittar Zirconia Blocks are an all ceramic core material made of high bisque fired Zirconia Oxide (ZrO_2), and are provided in either block, rod or disk shape. CAD/CAM fabrication of the core material can then be used to produce copings and / or substrates for fixed all ceramic dental restorations above the gum line. The material is used for the manufacturing of inlays, onlays, veneers, crowns and bridges. The material is then fired in an oven to harden the ZrO_2. The milling and final oven hardening process (i.e., sintering) is completed by the end user.

Intended Use

Bittar Zirconia Blocks 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.

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

The Bittar Zirconia Blocks 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

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

DEC 30 2008

Re: K082652
Trade/Device Name: Bittar Zirconia Blocks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: December 12, 2008
Received: December 24, 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): K082652

Device Name:

Bittar Zirconia Blocks

Type / Model: BZ

Shapes: Block, Rod & Disc

Sizes: Multiple

Indications for Use:

Bittar Zirconia Blocks 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)

for M. Susan Runner, DDS
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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