Zirconia Dental Ceramics

EMERGO GROUP

K111291 JUL 20 2011

SECTION 5 – 510(k) SUMMARY

Submission Correspondent

Company Name:	Emergo Group, Inc.
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Submission Date:	April 22, 2011
Website:	www.emergogroup.com/

Submission Sponsor

Company Name:	Qinhuangdao Aidite High-Technical Ceramics Co.
Company Address:	12 North of West Ring Road - Economic and Technological Development Zone Qinhuangdao City
Country:	China
Phone:	0086-335-8587898
Fax:	0086-335-8587198
Website:	www.zro2blocks.com/

Device Classification

Device Sponsor:	Qinhuangdao Aidite High-Technical Ceramics Co.
Device Trade Name:	Aidite Zirconia Dental Ceramics
Product Classification Name:	Powder, Porcelain
Product Code:	EIH
Regulation Name:	Porcelain powder for clinical use
Regulation Number:	872.6660
Classification Panel:	Dental Devices

Intended Use

Aidite Zirconia Dental Ceramics are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

Predicate Device

Upcera Zirconia Blanks (K093560)

Device Description

Aidite Zirconia Dental Ceramics are derived from zirconia powder that has been processed via uni-aixial die pressing, followed by iso-static pressing, to achieve various shapes of uniform density and distribution. The ceramic blocks can be fabricated into various prosthetic dental devices. Physical and mechanical properties for Aidite Zirconia Dental Ceramics are shown in **Table 5-1** and are similar in nature to the predicate device.

Table 5-1
Physical & Mechanical Properties
Aidite Zirconia Dental Ceramics

ZrO_2	< 96 % wt
Y_2O_3	> 4%
HfO_2	> 1%
Al_2O_3	< 1%
SiO_2	< 0.02%
Crystal Morphology	Tetragonal
Color	White
Density (pre sintering)	3.10 g/cm^3
Density (post sintering)	6.05 g/cm^3
Fracture Toughness (pre sintering)	55 Mpa
Fracture Toughness (post sintering)	1200 Mpa
Elastic modulus (post sintering)	210 Gpa
Sintering temperature	1480°C
Shrinkage (pre sintering)	20.00%
Shrinkage (post sintering)	22.00%
Porosity	0%

Aidite Zirconia Dental Ceramics are offered in seven (7) different product families of shapes and a multitude of different sizes as shown below in **Figure 1** and **Table 5-2** and are capable of being machined into complex dental shapes using modern machining methods, and are similar to the sizes and shapes of the predicate device. The one exception is the AS-XND System of

blocks is pre-mounted on mandrels. Any difference in the net shapes and dimensions between Aidite Zirconia Dental Ceramics and those offered by the manufacturer of the predicate devices are incidental to the performance of the final dental prosthetic devices that will be fabricated from them.

Figure 1
Aidite Zirconia Dental Ceramics

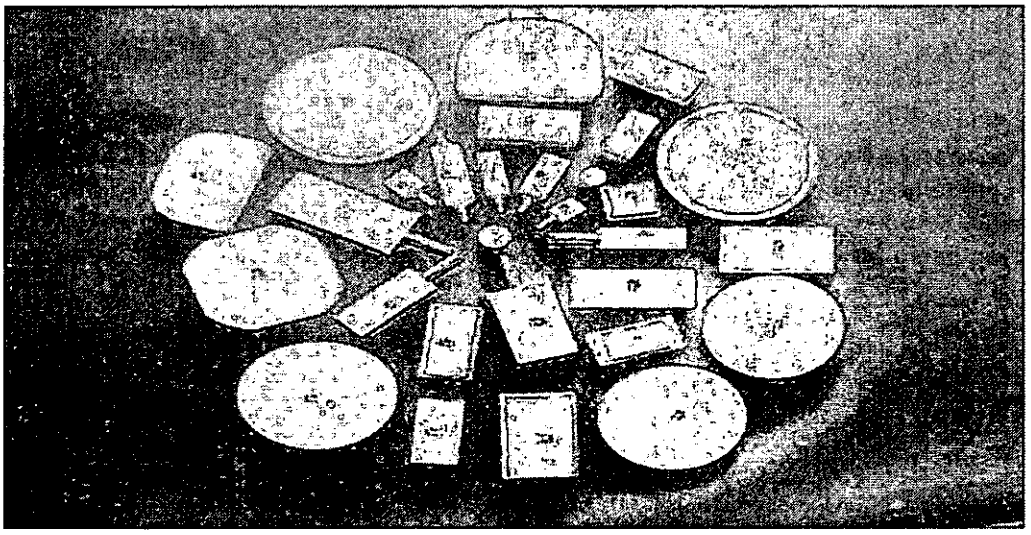

Table 5-2
Aidite Zirconia Dental Ceramics Product Family

Family	Shapes & Sizes Available
AC System	Blocks: 20 x 26.5 x 25 to 25 x 72 x 40 (mm)
AF System	Blocks: 29 x 58 x 16 to 40 x 85 x 22 (mm) Discs: 95 x 10 to 100 x 25 (mm)
AG System	Blocks: 20 x 40 x 16 to 20 x 65 x 30 (mm) Discs: 98 x 12 to 98 x 20 (mm) Spheres: 90 x 12 x 71 to 90 x 25 x 71 (mm)
AK-KAVA System	Blocks: 20 x 42 x 16 to 16 x 60 x 20 (mm) Rods: 16 x 16 to 20 x 20 (mm)
AS-XND System	Blocks: 14 x 20 x 15 to 20 x 65 x 25 (mm) (with mandrel)
AW-WLD System	Discs: 98 x 10 to 98 x 25 (mm)
AZ-KFS System	Blocks: 25 x 43 x 16 to 36 x 75 x 16 (mm) Rods: 23 x 16 (mm) Spheres: 87 x 16 x 56 to 93 x 16 x 75 (mm)

Product Performance Testing

Aidite Zirconia Dental Ceramics have been tested for their physical and chemical properties in

accordance with ISO 6872 and BS EN 1641, as well as biocompatibility in accordance with ISO 10993-1.

Clinical Testing

Clinical testing was not performed for Aidite Zirconia Dental Ceramics as part of the Pre-market Notification requirements for this submission, as dental ceramics that fall under FDA product code EIH have a long history of safe and effective use in the US. The raw materials used in Aidite Zirconia Dental Ceramics are identical to the raw material used in the predicate device and are sourced from the same raw material supplier in Japan, and do not raise any questions regarding their safety and effectiveness as compared to the predicate device.

Substantial Equivalence

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, and it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between Aidite Zirconia Dental Ceramics and the predicate device do not raise any questions regarding its safety and effectiveness. Aidite Zirconia Dental Ceramics, as designed and manufactured, therefore are determined to be substantially equivalent to Upcera Zirconia Blanks previously cleared under K093560.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Qinhuagdao Aidite High-Technical Ceramics Company, Limited
C/O Mr. Stuart R. Goldman
Emergo Group, Incorporated
611 5th Street, Third Floor
Austin, Texas 78701

JUL 20 2011

Re: K111291
Trade/Device Name: Aidite Zirconia Dental Ceramics
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH and ELL
Dated: April 22, 2011
Received: May 6, 2011

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. 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 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EMERGO GROUP

Zirconia Dental Ceramics

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K111291

Aidite Zirconia Dental Ceramics are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K111291