JENSEN
DENTAL

K112806

DEC - 1 2011

Section E **510(k) SUMMARY**

Submitted by:	Jensen Industries 50 Stillman Road North Haven CT 06473 (203) 239-2090 phone (203) 234-7630 fax Contact: Gary Phelps
Date Prepared:	September 19, 2011
Device Name:	Jensen Zirconia
Common Name:	Dental Ceramic
Classification Name:	Porcelain powder for clinical use (21 CFR 872.6660)
Classification:	Class II
Product Code:	EIH
Predicate Devices	Lava Frame: 510(k) number K011394

Device Description

Jensen Zirconia ceramic is pressed and sintered blocks of Yttria stabilized Zirconia used to make copings and full contour crowns for dental restorations.
Restorations are fabricated according to a dental impression scanned into a computing device. By CAD/CAM technology, the blocks are machined in an automated milling machine. After machining, the units are heat treated.
Full contour units may then be stained and glazed with available finishing materials. Coping units can be completed by conventional veneering with available Zr compatible dental porcelains and stained and glazed.

Indications for use

Jensen Zirconia ceramic consists of pressed Zirconia Yttrium blocks for milling full contour crowns, crown and bridge substructures suitable for veneering to produce finished prostheses and implant superstructures for replacement of missing / damaged dentition

Comparison to predicate device

Data has been presented to demonstrate that the respective mechanical properties, chemical qualities, and the indications for use make Jensen Zirconia substantially equivalent to the predicate device LAVA Frame. The safety and effectiveness of Jensen Zirconia, being determined by the shared chemical qualities and mechanical properties, is therefore equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Gary Phelps
Quality Assurance Manager
Jensen Industries, Inc.
50 Stillman Road
North Haven, CT 06473

DEC - 1 2011

Re: K112806
Trade/Device Name: Jensen Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 19, 2011
Received: September 28, 2011

Dear Mr. Phelps:

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

Indications for Use

510(k) Number (if known): K112806

Device Name: Jensen Zirconia

Indications for Use: Jensen Zirconia consists of pressed Zirconia – Yttrium blocks intended for milling of full contour crowns, crown and bridge substructures and implant super structures to produce prostheses for replacement of missing / damaged dentition.

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

ivision Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K112806