

K070114

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

MAR 01 2007

Date Prepared: January 4, 2007

Device Name: **Creation CP-ZI Porcelain**
Common Name: Dental Porcelain
Classification: Class II
Product Code: EIH

Predicate Devices Willi Geller Creation CP: 510(k) number K043221
Willi Geller Creation ZI: 510(k) number K043201

Device Description

Creation CP-ZI porcelain consists of pressable ceramic pellets that are pressed onto zirconia frames by dental technicians to fabricate full ceramic crowns and bridges. *Creation CP-ZI* is also suitable as a stand-alone press ceramic for fabricating inlays and onlays. Data has been presented to demonstrate that the respective mechanical properties, chemical qualities, and the indications for use make *Creation CP-ZI* substantially equivalent to the predicate devices *Willi Geller Creation CP* and *Willi Geller Creation ZI* porcelains. The safety and effectiveness of *Creation CP-ZI*, being determined by the shared chemical qualities and mechanical properties, is therefore equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 01 2007

Re: K070114
Trade/Device Name: Creation CP-ZI Porcelain
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 04, 2007
Received: January 19, 2007

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.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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,



fr

Chiu S. Lin, PhD
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): K070114

Device Name: Creation CP-ZI Porcelain

Indications for Use: Creation CP-ZI Porcelain is a pressable ceramic material intended to be used by dental technicians to construct veneers, inlays and ceramic crowns. CP-ZI can be pressed to zirconium oxide ceramic substructures for construction of ceramic crowns and bridges.

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)

Supra Rama
K070114

Page 1 of 1