OCT 22 1998

K981490

SUMMARY OF DATA

Willi Geller Creation porcelain is a dental ceramic that is used by dental technicians to fabricate dental restorations including porcelain fused to metal crowns and bridges, laminate veneers, and inlays. The product is substantially equivalent to the Willi Geller Creation ceramic which was cleared via 510(k) #K900209.

The ceramic powders in the Creation porcelain system are composed in varying proportions of silicon dioxide, aluminum oxide, sodium oxide, potassium oxide, tin oxide, barium oxide, and iron oxide. Chemically stable mixed metal oxides, including spinel, baddeleyit, zircon, and periclase phases of zirconium, iron, cobalt, chromium, yttrium, cerium, nickel, and zinc oxides, are used in trace amounts for pigmentation. The paste opaques are comprised of ceramic powder fitting this description suspended in glycerol, zinc chloride, sodium acetate, propandiol, and aerosil. The stains are composed of silicon dioxide, aluminum oxide, potassium oxide, tin oxide, barium oxide, iron oxide, and calcium oxide, and chemically stable mixed metal oxides for pigmentation. The modeling liquid is composed of zinc chloride and water. The shoulder liquid is composed of tylose and water. The glaze liquid is composed of methylethylene glycol and water. The opaque liquid is composed of zinc chloride, water, and sodium chloride. The vehicle used in the paste opaques and the liquids are evaporated during use, and are not incorporated into devices manufactured with the porcelain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

Mr. John M. Slanski
Research and Development
JENSEN Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K981490
Trade Name: Willi Geller Creation Porcelain
Regulatory Class: II
Product Code: EIH
Dated: July 27, 1998
Received: August 6, 1998

Dear Mr. Slanski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Patricia Cucanato /for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): Not known

Device Name: Willi Geller Ceramic Porcelain

Indications For Use:

The product is intended for use in fabricating oral crowns and bridges and laminate veneers and inlays for dental use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerald Shupp

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981490

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)