K040567

APR 2 2 2004

510(k) SUMMARY

Submitted by:	GC America Inc
Contact Person:	Terry L. Joritz
Date Prepared:	February 24, 2004
Proprietary Name:	GC Initial MC, GC Initial AL, GC Initial LF
Common Name:	Dental Ceramic Material
Device Classification Name:	Porcelain powder for dental use
Classification :	Class II medical device
Product Code :	EIH Regulation Number 872.6660
Legally marketed equiv. devices:	Willi Geller Creation& CC Porcelain 510(k) #K981490 Willi Geller Creation& AV Porcelain 510(k) #K002041 Willi Geller Creation& LF Porcelain 510(k) #K002904
Description of the Device:	The GC Initial dental ceramic system is a feldspathic porcelain system based on partially crystalline but mostly vitreous materials derived from phyllosilicates such as potash or soda feldspar, several commercially available fluxes, and various refractive oxides for mechanical enhancement.
Intended Use of the Device:	The product is intended to be used by dental technicians to fabricate dental restorations including porcelain fused to metal or alumina based cores crowns and bridges, laminate veneers, and inlays.
Technological Characteristics	The GC Initial dental ceramic has identical technological characteristics to the Willi Geller Creation& porcelain system and indicates therefore the same harmless environmental properties as the predicate device. It also meets the appropriate ISO Standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 2 2004

Ms. Terry L. Joritz
Director, Regulatory Affairs and Quality Control
GC America, Incorporated
3737 West 127th Street
Alsip, Illinois 60803

Re: K040567
Trade/Device Name: GC Initial Dental Porcelain
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 02, 2004
Received: March 17, 2004

Dear Ms. Joritz:

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.

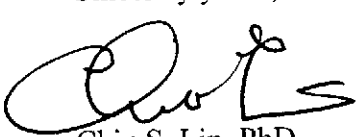
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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): K040567

Device Name: GC Initial Dental Porcelain

Indications for Use:

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

Prescription Use ✓ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert B Ochs DDS for Dr Susan Runner

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

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