

K091388

**510(k) Summary  
for  
MI Fil (GCUC-505)**

**Submitter Information:**

GC AMERICA INC.  
3737 W. 127<sup>th</sup> Street  
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.  
Phone: (708) 897-4042  
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Date Prepared: May 4, 2009

**Device Name:**

Proprietary Name: MI Fil (GCUC-505)  
Classification Name: Tooth Shade Resin Material  
Device Classification: Class II, 872.23690  
Produce Code: EBF

**Predicate Devices:**

Company	Device	K Number	Date Cleared
GC America Inc.	GRADIA DIRECT LoFlo	K042348	01/30/2003
GC America Inc.	GDLS-200 (Kalore)	K082434	11/14/2008
Ivoclar Vivadent, Inc.	TETRIC EVO CERAM	K042819	11/09/2004

**Description of Device:**

MI Fil (GCUC-505) is a light-cured nano-filled radiopaque composite resin filled in a syringe topped with a needle tip. The device is a flowable composite resin of normal consistency. The material is available in 17 shades.

**Indications for use:**

- Restoration of Class I, II, III, IV, V cavities
- Restoration of root surface caries
- Restorations in deciduous teeth
- Filling tunnel shaped cavities
- Sealing hypersensitive areas
- Liner/base/filling in cavity undercuts
- Sealant
- Fixing loose teeth
- Additions to composite restorations

**Description of Safety and Substantial Equivalence:**

The applicant device is substantially equivalent to the predicate devices in its intended use. They are all composite resins and are used for the restorations of both anterior and posterior teeth. They are also used as a filling material and sealant.



JUL 22 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mark Heiss, D. D. S.  
Director of New Business Development and Regulatory Affairs  
GC America, Incorporated  
3737 West 127<sup>th</sup> Street  
Alsip, Illinois 60803

Re: K091388  
Trade/Device Name: MI Fil (GCUC-505)  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF, EBC, LBH  
Dated: May 4, 2009  
Received: May 11, 2009

Dear Dr. Heiss:

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 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.

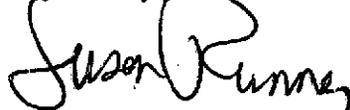
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S., M.A.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Section 6 – Indications for Use Statement

Indications for Use

510(k) Number (if known):

K091388

Device Name: MI Fil (GCUC-505)

Indications for Use:

Intended use

Restoration of Class I, II, III, IV, V cavities  
Restoration of root surface caries  
Restorations in deciduous teeth  
Filling tunnel shaped cavities  
Sealing hypersensitive areas  
Liner/base/filling in cavity undercuts  
Sealant  
Splinting mobile teeth  
Additions to composite restorations

Prescription Use   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(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)

Keri Muly for HSR

(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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