DATE OF SUBMISSION: January 25, 2013

OWNER: Pulpdent Corporation

CONTACT: 
Kenneth J. Berk 
80 Oakland Street 
PO Box 780 
Watertown, MA 02472 USA

DEVICE:
Trade Name: Pulpdent RMGI Fill 
Classification Name: Dental cement 
FDA Product Code: EMA, 21 CFR Part 872.3275

PREDICATE DEVICES:
Pulpdent RMGI Low Viscosity 
3M ESPE Ketac Nano Glass Ionomer Restorative 
GC Fuji Filling LC

INTENDED USE:
Pulpdent RMGI Fill is a resin-modified glass ionomer preparation used by dental professionals as a restorative filling material.

DESCRIPTION:
Pulpdent RMGI Fill is a resin-modified glass ionomer preparation with both a bioactive resin matrix and bioactive glass fillers. In this context 'bioactive' refers to the release of beneficial ions from the resin and glass fillers into the oral environment. As a resin-modified glass ionomer, Pulpdent RMGI Fill has three setting mechanisms: light cure, self-cure resin chemistry, and acid-base glass ionomer reaction. It contains no Bisphenol A, no BisGMA and no BPA derivatives. Pulpdent RMGI Fill is a paste-paste formulation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.

SUMMARY OF PERFORMANCE TESTING – BENCH

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexural strength</td>
<td>102.0 MPa</td>
</tr>
<tr>
<td>Flexural modulus</td>
<td>4.3 GPa</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>280.0 MPa</td>
</tr>
<tr>
<td>Diametral tensile strength</td>
<td>42.0 MPa</td>
</tr>
<tr>
<td>Light cure set time</td>
<td>20 seconds</td>
</tr>
<tr>
<td>Self-cure set time (intraoral)</td>
<td>2 minutes, 20 seconds at 37°C</td>
</tr>
<tr>
<td>Self-cure set time (extra-oral)</td>
<td>3 minutes, 30 seconds from beginning of mix at 20°C</td>
</tr>
<tr>
<td>Shear bond strength</td>
<td>28 MPa (RMGI Fill to composite)</td>
</tr>
<tr>
<td>Radiopacity</td>
<td>Equivalent to 2 mm aluminum</td>
</tr>
<tr>
<td>Polymerization shrinkage</td>
<td>1.7%</td>
</tr>
</tbody>
</table>
COMPARISON WITH PREDICATE PRODUCTS:

*Pulpdent RMGI Fill* is substantially equivalent in design, composition, performance and intended use to the predicate products:

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Intended Use</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pulpdent RMGI Fill</strong></td>
<td>Resin-modified glass ionomer in two pastes</td>
<td>Dental restorative</td>
<td>Part A: Diurethane dimethacrylate and other methacrylate-based monomers and oligomers; polyacrylic acid/maleic acid copolymer, water, barium borosilicate glass, silica, reducing agents, photoinitiator, colorants. Part B: Diurethane dimethacrylate and other methacrylate-based monomers and oligomers; aluminofluorosilicate ionomer glass, silica, oxidizing agents.</td>
</tr>
<tr>
<td><strong>Pulpdent RMGI Low Viscosity</strong></td>
<td>Resin-modified glass ionomer in two pastes</td>
<td>Dental liner, base or luting agent</td>
<td>Part A: Diurethane dimethacrylate and other methacrylate-based monomers and oligomers, polyacrylic acid/maleic acid copolymer, water, barium borosilicate glass, silica, reducing agents, photoinitiator. Part B: Diurethane dimethacrylate and other methacrylate-based monomers and oligomers, aluminofluorosilicate ionomer glass, silica, oxidizing agents.</td>
</tr>
<tr>
<td><strong>3M Espe</strong></td>
<td>Light cure, resin-modified glass ionomer in two pastes</td>
<td>Dental restorative</td>
<td>Part A: Silane-treated glass, zirconia and silica; ionomer glass; BisGMA; PEGDMA; HEMA; TEGDMA. Part B: Silane-treated ceramic; co-polymer of acrylic and itaconic acids; HEMA; water.</td>
</tr>
<tr>
<td><strong>GC</strong></td>
<td>Light cure, resin-modified glass ionomer in two pastes</td>
<td>Dental restorative</td>
<td>Part A: Aluminofluorosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate.</td>
</tr>
</tbody>
</table>
From the above comparisons and the bench testing, it can be concluded that Pulpdent RMGI Fill is substantially equivalent in design, composition, performance and intended use to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3275 and have been used by dental professionals for more than 20 years. A search of the relevant scientific literature shows that resin-modified glass ionomers, used as a restorative filling material, have been extensively studied. See References below.

REFERENCES

Specific to Pulpdent RMGI Fill and RMGI Low Viscosity (K123265)


General


March 29, 2013

Mr. Kenneth J. Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
PO Box 780
WATERTOWN MA 02472 USA

Re: K130223
Trade/Device Name: Pulpdent RMGI FILL
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 25, 2013
Received: February 6, 2013

Dear Mr. Berk:

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](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” (21 CFR 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](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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

Kwame O. Ulmer -S

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known):

Device Name: Pulpdent RMGI FILL

Indications for Use:

_Pulpdent RMGI Fill_ is a resin-modified glass ionomer preparation used by dental professionals as filling material in dental restorations.

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)

Andrew I. Steen
2013.03.26 14:46:33-04:00

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

510(k) Number: K130223