DEC 7 2012

PULPDENT CORPORATION

80 Oakland Street
Watertown, MA 02472
USA

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510(k) SUMMARY

K123265

DATE OF SUBMISSION: October 5, 2012

OWNER: ***Pulpdent Corporation***

CONTACT:

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

Telephone: 617-926-6666
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DEVICE:

Trade Name: ***RMGI Low Viscosity***
Classification Name: Dental cement
FDA Product Code: EMA, 21 CFR Part 872.3275

PREDICATE DEVICES:

Pulpdent Tuff-Temp 2.0
3M RelyX Luting Plus
3M Vitrebond Plus LC
GC Fuji Lining LC
GC Fuji Plus Lining Capsule

INTENDED USE:

Pulpdent RMGI Low Viscosity is a resin-modified glass ionomer preparation used by dental professionals as a liner, base or luting material in dental restorations.

DESCRIPTION:

Pulpdent RMGI Low Viscosity 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, *RMGI Low Viscosity* has three setting mechanisms: light cure, self-cure resin chemistry, and acid-base glass ionomer reaction. It contains no Bisphenol A, no Bis-GMA and no BPA derivatives. *RMGI Low Viscosity* is a paste-paste formulation provided in an automix syringe.

SUMMARY OF PERFORMANCE TESTING – BENCH

	Self-cure	Light cure
Flexural strength	81.0 MPa	88.0 MPa
Compressive strength	208.0 MPa	239 MPa
Flexural modulus	3.7 GPa	Not tested
Diametral tensile strength	38.0 MPa	36.0 MPa
Working time	2 min 30 seconds	Not applicable
Setting time	3-3.5 min from beginning of mix	20 seconds
Radiopacity	Equivalent to 2 mm aluminum	Equivalent to 2 mm aluminum

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COMPARISON WITH PREDICATE PRODUCTS:

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

Product	Description	Intended Use	Composition
Pulpdent RMGI Low Viscosity	Resin-modified glass ionomer in two pastes	Dental liner, base or luting agent.	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, aluminoflurosilicate ionomer glass, silica, oxidizing agents.
Pulpdent Tuff Temp 2.0 K120784	Glass-filled resin in two parts with photo-initiator and self-cure chemistry.	Temporary crown and bridge material	Diurethane dimethacrylate and other methacrylate monomers and oligomers in two pastes.
3M RelyX Luting Plus Automix K111185	Resin-modified glass ionomer in two pastes	Dental cement / luting agent	Part A: Fluoroaluminosilicate glass, HEMA, water, opacifying agent and reducing agent Part B: Zirconia silica filler, methacrylated polycarboxylic acid, HEMA, Bis-GMA, water, potassium persulfate, photoinitiator.
3M Vitrebond Plus Glass Ionomer Liner K011200	Resin-modified glass ionomer in two parts: paste and liquid	Dental cavity liner / base and cement	Paste HEMA, BIS-GMA, fluoroaluminosilicate glass, water and initiators. Liquid Methacrylate-modified polycarboxylic acid, water, HEMA, photoinitiator.
GC Fuji Lining LC K 020117, K051427	Resin-modified glass ionomer in two parts: powder and liquid	Cavity liner/base and dental cement	Powder: Alumino-silicate glass Liquid: HEMA, polyacrylic acid, water, UDMA, photo-initiator.
GC Fuji Plus Lining Capsule K 993973	Resin-modified glass ionomer in two parts: powder and liquid	Cavity liner/base and dental cement	Powder: Aluminofluorosilicate glass. Liquid: Polyacrylic acid, HEMA, tartaric acid, dimethacrylate, water.

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	Compressive Strength MPa	Flexural Strength MPa	Flexural Modulus GPa	Diametral Tensile strength (DTS) MPa
Pulpdent RMGI Low Viscosity (auto cure)	**208**	**81.0**	**3.7**	**38**
Pulpdent RMGI Low Viscosity (light cure)	**239**	**88.0**		**36**
Pulpdent Tuff Temp 2.0	205.0	84.0		---
3M-RelyX Luting Plus	110	27		15
3M–Vitrebond Plus LC	114	28		18
GC Fuji Lining LC	135	26		12
GC–Fuji Plus Lining Capsule	156	31		15

CONCLUSION:

From the above comparisons and the bench testing, it can be concluded that *Pulpdent RMGI Low Viscosity* 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 for cavity lining and luting have been extensively studied. See References below.

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Specific to Pulpdent RMGI Low Viscosity

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3. Pameijer CH et al. Marginal bacterial leakage with RMGI filled restorations and castings cemented with a RMGI luting cement. University of El Salvador/Argentine Dental Association, Buenos Aires, Argentina. 2012 Jun.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 7, 2012

Mr. Kenneth J. Berk
Director
Pulpdent Corporation
80 Oakland Street
Watertown, Massachusetts 02472

Re: K123265
Trade/Device Name: Pulpdent RMGI Low Viscosity
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement, Cavity Liner
Regulatory Class: II
Product Code: EMA, EJK
Dated: October 16, 2012
Received: October 19, 2012

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 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/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.

Sincerely yours,

Kwame O. Ulmer

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 Low Viscosity***

Indications for Use:

Pulpdent RMGI Low Viscosity is a resin-modified glass ionomer preparation used by dental professionals as a liner, base or luting material in dental restorations.

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

Susan Runner DDS, MA 2012.12.07 16:19:29 -05'00'

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

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