

KV30223

PULPDENT CORPORATION

80 Oakland Street
Watertown, MA 02472
USA

Tel: 617 926 6666
Fax: 617 926 6262
Email: Pulpdent@pulpdent.com

510(k) SUMMARY

DATE OF SUBMISSION: January 25, 2013

MAR 29 2013

OWNER: *Pulpdent Corporation*

CONTACT:

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

Telephone: 617-926-6666
Fax: 617-926-6262
Email: ken@pulpdent.com

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

Flexural strength	102.0 MPa
Flexural modulus	4.3 GPa
Compressive strength	280.0 MPa
Diametral tensile strength	42.0 MPa
Light cure set time	20 seconds
Self-cure set time (intraoral)	2 minutes, 20 seconds at 37°C
Self-cure set time (extra-oral)	3 minutes, 30 seconds from beginning of mix at 20°C
Shear bond strength	28 MPa (RMGI Fill to composite)
Radiopacity	Equivalent to 2 mm aluminum
Polymerization shrinkage	1.7%

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COMPARISON WITH PREDICATE PRODUCTS:

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

Product	Description	Intended Use	Composition
Pulpdent RMGI Fill	Resin-modified glass ionomer in two pastes	Dental restorative	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.
<i>Pulpdent</i> RMGI Low Viscosity K123265	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, aluminofluorosilicate ionomer glass, silica, oxidizing agents.
<i>3M Espe</i> Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	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.
GC Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminofluorosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate.

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	Compressive Strength MPa	Flexural Strength MPa	Flexural Modulus GPa	Diametral Tensile strength (DTS) MPa
Pulpdent RMGI Fill	280	102	4.3	42.0
Pulpdent RMGI Low Viscosity	239	88		36
3M ESPE Ketac Nano	236	35	5.4	32
GC Fuji Filling LC	165	28	12.3	15

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)**

1. Pameijer CH, et al. Biocompatibility of four experimental formulations [including Pulpdent RMGI Fill] in subcutaneous connective tissue of rats. Pulpdent Corporation. 2011 Nov.
2. Pameijer CH. Report on the retention of Embrace WetBond cement and a RMGI cement (Pulpdent). Pulpdent Corporation 2012 Aug.
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.
4. Pameijer CH. Microleakage of four experimental resin-modified glass ionomer restorative materials. Pulpdent Corporation. 2011 Apr.
5. Pameijer CH, Zmener O. Histopathological evaluation of RMGI cement, auto- and light-cured, used as a luting agent. A subhuman primate study. Pulpdent Corporation. March 2011.

General

6. Booth SE. Surface properties and the bioactivity of glass-ionomer dental cements and related materials. PhD Thesis, University of Greenwich. 2010.

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23. Nicholson JW, Czarnecka B. The biocompatibility of resin-modified glass-ionomer cements for dentistry. *Dent Mater.* 2008 Dec;24(12):1702-8.
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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 20993-0002

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.

Page 2 – Mr. Berk

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/ucml15809.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 -S** for

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
(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)

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

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

Page 1 of 1

510(k) Number: K130223

K130223



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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 3 – Mr. Berk

Concurrence & Template History Page

[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K130223

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Girish Kumar 2013.03.26 13:41:26 -04'00'
Branch Chief Sign-Off	Andrew L Steen 2013.03.26 15:04:39 -04'00'
Division Sign-Off	Kwame O. Ulmer -S 2013.03.29 13:12:54 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".

Indications for Use

510(k) Number (if known):

Device Name: *Pulpdent RMGI FILL*

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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(21 CFR 807 Subpart C)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: K130223

PULPDENT CORPORATION

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January 30, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

FEB 01 2013

Received

Re: K130223, Traditional 510(k) Premarket Submission for *Pulpdent RMGI Fill*

Dear Sir / Madam,

This submission serves as our 510(k) Premarket Notification for a new Pulpdent product, *RMGI Fill*, in compliance with Title 21 of the Code of Federal Regulations.

All information contained in this submission that is enclosed with a black border should be considered CONFIDENTIAL COMMERCIAL INFORMATION for all purposes.

Pulpdent Corporation, at the address below, is engaged in the business of manufacturing, importing and distributing dental products intended for use only by dentists and their ancillary personnel in the dental office and laboratory (21 CFR 801 Subpart D).

SUBMITTER / MANUFACTURER	<i>PULPDENT CORPORATION</i> 80 Oakland Street Watertown, MA 02472 USA
REGISTRATION	1215305
CONTACT	Kenneth J. Berk, Director TEL.: 617-926-6666 / FAX: 617-926-6262 ken@pulpdent.com
DEVICE NAME	Pulpdent RMGI Fill
CLASSIFICATION	Class II Device / Dental Panel / 76

Please see EXHIBITS 1 through 10 in hard copy and electronic files 001_ to 045_ in the Replacement eCopy for the contents of the submission. The Replacement eCopy is an exact duplicate of the paper copy except that the MSDS for component materials are only included in the electronic version. A placeholder was provided in Exhibit 8 of the paper copy referring back to the eCopy for that information.

Sincerely,



Kenneth J. Berk
Director, *Pulpdent Corporation*

PULPDENT CORPORATION

80 Oakland Street
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February 4, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

FEB 06 2013

Received

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SUBMITTER /
MANUFACTURER

PULPDENT CORPORATION

80 Oakland Street
Watertown, MA 02472 USA

REGISTRATION

1215305

CONTACT

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DEVICE NAME

Pulpdent RMGI Fill

CLASSIFICATION

Class II Device / Dental Panel / 76

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Sincerely,



Kenneth J. Berk
Director, *Pulpdent Corporation*

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) 3 Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) PULPDENT CORP 80 OAKLAND STREET P O BOX 780 WATERTOWN MA 02472 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3633	2. CONTACT NAME Kenneth Berk 2.1 E-MAIL ADDRESS ken@pulpdent.com 2.2 TELEPHONE NUMBER (include Area code) 617-9266666 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 617-9266262	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <u>Select an application type:</u> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ 30-Day Notice 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) ☐ NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). ☐ YES ☒ NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)		

22-Jan-2013

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

FORM FDA 3514 (1/13)

Page 1 of 5 Pages

Contact Title		Contact E-mail Address	
Contact Name			
City	State / Province	ZIP Code	Country
Street Address		FAX Number (including area code)	
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Company / Institution Name			
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Contact Title		Contact E-mail Address	
Contact Name			
City	State / Province	ZIP/Postal Code	Country
Street Address		FAX Number (including area code)	
Division Name (if applicable)		Phone Number (including area code)	
Company / Institution Name		Establishment Registration Number (if known)	
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Have you used or cited Standards in your submission? ☐ Yes ☐ No (If Yes, please complete Section I, Page 5)			
IDE		Humanitarian Device Exemption (HDE)	
☐ Original Submission ☐ Amendment ☐ Supplement		☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	
☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement		☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	
PMA		PMA & HDE Supplement	
☒ Original Submission ☐ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party		☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	
510(k)		PDP	
☒ Original Submission ☐ Request for Feedback ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (specify):		☐ Original Submission ☐ Amendment ☐ Supplement ☐ 513(g) ☐ Other (describe submission):	
Other Submission		Class II Exemption Petition	
☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment		☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	
Class III Designation (De Novo)		Class II Exemption Petition	
☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment		☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	
Evaluation of Automatic		Class II Exemption Petition	
☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment		☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	
Other Submission		Class II Exemption Petition	
☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment		☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	

TYPE OF SUBMISSION

Date of Submission

January 25, 2013

User Fee Payment ID Number

(4) (g)

FDA Submission Document Number (if known)

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approval

OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on page 5.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE			SECTION D2 REASON FOR APPLICATION - IDE			SECTION D3 REASON FOR SUBMISSION - 510(k)		
☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site			☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (specify below)			☐ Response to FDA correspondence:		
☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (specify below)			☐ Labeling change: ☐ Instructions ☐ Indications ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (specify below)			☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final		
☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager			☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment			☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address		
☐ New Device ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access			☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final			☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of ☐ Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing		
☐ Other Reason (specify):			☐ Other Reason (specify):			☐ Other Reason (specify):		
☒ New Device ☐ Additional or Expanded Indications ☐ Change in Technology			☐ Other Reason (specify):			☐ Other Reason (specify):		

FORM FDA 3514 (1/13)

Page 3 of 5 Pages

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS									
Product codes of devices to which substantial equivalence is claimed									
1	EMA	2		3		4		8	
Information on devices to which substantial equivalence is claimed (if known)									
510(k) Number		Trade or Proprietary or Model Name		Manufacturer					
1	K123265	1	RMGI LOW VISCOSITY	1	PULPENT				
2	K052235	2	KETAC NANO GLASS IONOMER RESTORATIVE	2	3M ESPE				
3	K051427	3	FUJI FILLING LC	3	GC				
4		4		4					
5		5		5					
6		6		6					
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS									
Common or usual name or classification name									
Dental Cement									
Trade or Proprietary or Model Name for This Device									
Model Number									
1	RMGI Fill	1		1					
2		2		2					
3		3		3					
4		4		4					
5		5		5					
FDA document numbers of all prior related submissions (regardless of outcome)									
1	K123265	2	3	4	5	6		11	12
Data Included in Submission									
☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials									
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS									
Product Code		C.F.R. Section (if applicable)		Device Class					
EMA		872.3275							
Classification Panel									
Dental									
Indications (from labeling) Pulpent RMGI Fill is a resin-modified glass ionomer preparation used by dental professionals as filling material in dental restorations.									

FORM FDA 3514 (1/13)

Add Continuation Page

Page 4 of 5 Pages

Contact Name		Contact Title		Contact E-mail Address	
City		State / Province		ZIP Code	
Street Address		FAX Number (including area code)		Country	
Division Name (if applicable)		Phone Number (including area code)			
Company / Institution Name		Establishment Registration Number			
☐ Original ☐ Add ☐ Delete		☐ Facility Establishment Identifier (FEI) Number ☐ Manufacturer ☐ Contract Manufacturer ☐ Repackager / Relabeler		☐ Contract Sterilizer ☐ Repackager / Relabeler	
Contact Name		Contact Title		Contact E-mail Address	
City		State / Province		ZIP Code	
Street Address		FAX Number (including area code)		Country	
Division Name (if applicable)		Phone Number (including area code)			
Company / Institution Name		Establishment Registration Number			
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Street Address		FAX Number (including area code)		Country	
Division Name (if applicable)		Phone Number (including area code)			
Company / Institution Name		Establishment Registration Number			
☒ Original ☐ Add ☐ Delete		☐ Facility Establishment Identifier (FEI) Number ☒ Manufacturer ☐ Contract Manufacturer ☐ Repackager / Relabeler		☐ Contract Sterilizer ☐ Repackager / Relabeler	

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

Please include any additional standards to be cited on a separate page.

1	Standards No.	Standards Organization	Standards Title	Version	Date
	9917-2	ISO	Dentistry - Water-based cements - Part 2: Resin-modified cements.	Second edition	April 15, 2010
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

SECTION I UTILIZATION OF STANDARDS

PULPDENT CORPORATION

80 Oakland Street
Watertown, MA 02472
USA

TEL: 617-926-6666
FAX: 617-926-6262
Pulpdent@pulpdent.com

February 4, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K130223, Traditional 510(k) Premarket Submission for *Pulpdent RMGI Fill*

Dear Sir / Madam,

This submission serves as our 510(k) Premarket Notification for a new Pulpdent product, *RMGI Fill*, in compliance with Title 21 of the Code of Federal Regulations.

All information contained in this submission that is enclosed with a black border should be considered CONFIDENTIAL COMMERCIAL INFORMATION for all purposes.

Pulpdent Corporation, at the address below, is engaged in the business of manufacturing, importing and distributing dental products intended for use only by dentists and their ancillary personnel in the dental office and laboratory (21 CFR 801 Subpart D).

SUBMITTER / MANUFACTURER	<i>PULPDENT CORPORATION</i> 80 Oakland Street Watertown, MA 02472 USA
REGISTRATION	1215305
CONTACT	Kenneth J. Berk, Director TEL.: 617-926-6666 / FAX: 617-926-6262 ken@pulpdent.com
DEVICE NAME	Pulpdent RMGI Fill
CLASSIFICATION	Class II Device / Dental Panel / 76

Please see EXHIBITS 1 through 10 in hard copy and electronic files 001_ to 045_ in the Replacement eCopy for the contents of the submission. The Replacement eCopy is an exact duplicate of the paper copy except that the MSDS for component materials are only included in the electronic version. A placeholder was provided in Exhibit 8 of the paper copy referring back to the eCopy for that information.

Sincerely,



Kenneth J. Berk
Director, *Pulpdent Corporation*

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
(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)

PULPDENT CORPORATION

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USA

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Fax: 617 926 6262
Email: Pulpdent@pulpdent.com

510(k) SUMMARY

DATE OF SUBMISSION: January 25, 2013

OWNER: *Pulpdent Corporation*

CONTACT:

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

Telephone: 617-926-6666
Fax: 617-926-6262
Email: ken@pulpdent.com

DEVICE:

Trade Name: *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, *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. *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

Flexural strength	102.0 MPa
Flexural modulus	4.3 GPa
Compressive strength	280.0 MPa
Diametral tensile strength	42.0 MPa
Light cure set time	20 seconds
Self-cure set time (intraoral)	2 minutes, 20 seconds at 37°C
Self-cure set time (extra-oral)	3 minutes, 30 seconds from beginning of mix at 20°C
Shear bond strength	28 MPa (RMGI Fill to composite)
Radiopacity	Equivalent to 2 mm aluminum
Polymerization shrinkage	1.7%

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COMPARISON WITH PREDICATE PRODUCTS:

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

Product	Description	Intended Use	Composition
Pulpdent RMGI Fill	Resin-modified glass ionomer in two pastes	Dental restorative	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.
<i>Pulpdent</i> RMGI Low Viscosity K123265	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, aluminofluorosilicate ionomer glass, silica, oxidizing agents.
3M Espe Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	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.
GC Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminofluorosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate.

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	Compressive Strength MPa	Flexural Strength MPa	Flexural Modulus GPa	Diametral Tensile strength (DTS) MPa
Pulpdent RMGI Fill	280	102	4.3	42.0
Pulpdent RMGI Low Viscosity	239	88		36
3M ESPE Ketac Nano	236	35	5.4	32
GC Fuji Filling LC	165	28	12.3	15

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)**

1. Pameijer CH, et al. Biocompatibility of four experimental formulations [including RMGI Fill] in subcutaneous connective tissue of rats. Pulpdent Corporation. 2011 Nov.
2. Pameijer CH. Report on the retention of Embrace WetBond cement and a RMGI cement (Pulpdent). Pulpdent Corporation 2012 Aug.
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.
4. Pameijer CH. Microleakage of four experimental resin-modified glass ionomer restorative materials. Pulpdent Corporation. 2011 Apr.
5. Pameijer CH, Zmener O. Histopathological evaluation of RMGI cement, auto- and light-cured, used as a luting agent. A subhuman primate study. Pulpdent Corporation. March 2011.

General

6. Booth SE. Surface properties and the bioactivity of glass-ionomer dental cements and related materials. PhD Thesis, University of Greenwich. 2010.

PULPDENT CORPORATION

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15. Hübel S, Mejàre I. Conventional versus resin-modified glass-ionomer cement for Class II restorations in primary molars. A 3-year clinical study. Int J Paediatr Dent. 2003 Jan;13(1):2-8.
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18. Loguercio AD, et al. Five-year double-blind randomized clinical evaluation of a resin-modified glass ionomer and a polyacid-modified resin in non-carious cervical lesions. J Adhes Dent. 2003 Winter;5(4):323-32.
19. Matsuya S, et al. Structure of bioactive glass and its application to glass ionomer cement. Dent Mater J. 1999 Jun;18(2):155-66.
20. Mitra SB, et al. Fluoride release and recharge behavior of a nano-filled resin-modified glass ionomer compared with that of other fluoride releasing materials. Am J Dent. 2011 Dec;24(6):372-8.
21. Mousavinasab SM, et al. Flexural strength and morphological characteristics of resin-modified glass-ionomer containing bioactive glass. J Contemp Dent Pract. 2011 Jan 1;12(1):41-6.

PULPDENT CORPORATION

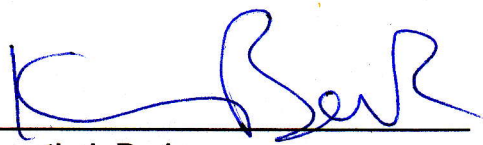
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22. Murray PE, et al. Restorative pulpal and repair responses. JADA 2001 Apr;132:482-91.
23. Nicholson JW, Czarnecka B. The biocompatibility of resin-modified glass-ionomer cements for dentistry. Dent Mater. 2008 Dec;24(12):1702-8.
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TRUTHFUL AND ACCURACY STATEMENT

Pursuant to 21 CFR 807.87(j), I, Kenneth J. Berk, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director of *Pulpdent Corporation*, and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.


Kenneth J. Berk

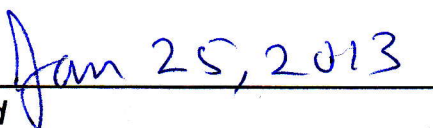

Dated

EXHIBIT 3

EXECUTIVE SUMMARY

Description and Intended Use

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, *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 that is used by dental professionals as a filling material in dental restorations.

Device Comparison with Predicate Products

Pulpdent RMGI Fill is substantially equivalent in design, composition, performance and intended use to the predicate products listed below. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3275.

Product	Description	Intended Use	Composition
Pulpdent RMGI Fill	Resin-modified glass ionomer in two pastes		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.
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, aluminofluorosilicate ionomer glass, silica, oxidizing agents.
3M Espe Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	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.
GC Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminofluorosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate.

Summary of Performance Testing – Bench

Flexural strength	102.0 MPa	Light cure set time	20 seconds
Flexural modulus	4.3 GPa	Self-cure set time	2 min 20 sec at 37°C (intraoral)
Compressive strength	280.0 MPa	Self-cure set time	3 min 30 sec at 20°C (extra-oral)
Diametral tensile strength	42.0 MPa	Radiopacity	Equivalent to 2 mm aluminum

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510 k Premarket Notification

008_Device Specification and Description.docx

Pulpdent RMGI Fill

EXHIBIT 3**DEVICE SPECIFICATION, DESCRIPTION, INTENDED USE, FORMULAS****PRODUCT SPECIFICATION**

PRODUCER NAME AND ADDRESS	PULPDENT CORPORATION 80 OAKLAND STREET WATERTOWN, MASSACHUSETTS 02472 USA
REGISTRATION	United States Food and Drug Administration Device Establishment Registration No. 1215305
CERTIFICATION	EC Certificate No. 9101 rev 2 issued by LNE/G-MED, effective 28 July 2011, for compliance with Directive 93/42/EEC, Annex II, Section 3; Certificate of Registration No. 9384 rev 3, issued by LNE/G-MED, effective 28 July 2011, for compliance with the requirements of ISO 13485:2003; Certificate of Registration No. 9385 rev 3, issued by LNE/G-MED effective 28 July 2011, certifying that the Pulpdent Quality Assurance System complies with the requirements of ISO 9001:2008.
TRADE NAME	<i>Pulpdent RMGI FILL</i>
SCIENTIFIC NAME	Resin-modified glass ionomer dental material
INTENDED USE	Dental filling material for restorations.
STANDARD	ISO 9917-2:2010 Dentistry – Water-based cements – Part 2: Resin-modified cements
US FOOD AND DRUG ADMINISTRATION	510k Pre-market Notification Class II Medical Device
EUROPEAN UNION	MDD ANNEX IX: CE Marked Class IIA Medical Device.
LOT NUMBER	ISO format: <i>Year-Month-Day</i> of manufacture
EXPIRATION DATE	Two years after date of manufacture
STORAGE CONDITIONS	Store tightly capped at cool room temperature. Avoid direct, intense light and cross-contamination of parts.
CONTAINER / PACKAGING	Dual-barrel syringe, mixing and applicator tips
SIDE EFFECTS AND CAUTIONS	Minimal health hazard under normal conditions of use. Material may be irritating to eyes, mucous membranes or skin on contact; may be sensitizing with prolonged and/or repeated exposure.

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510 k Premarket Notification

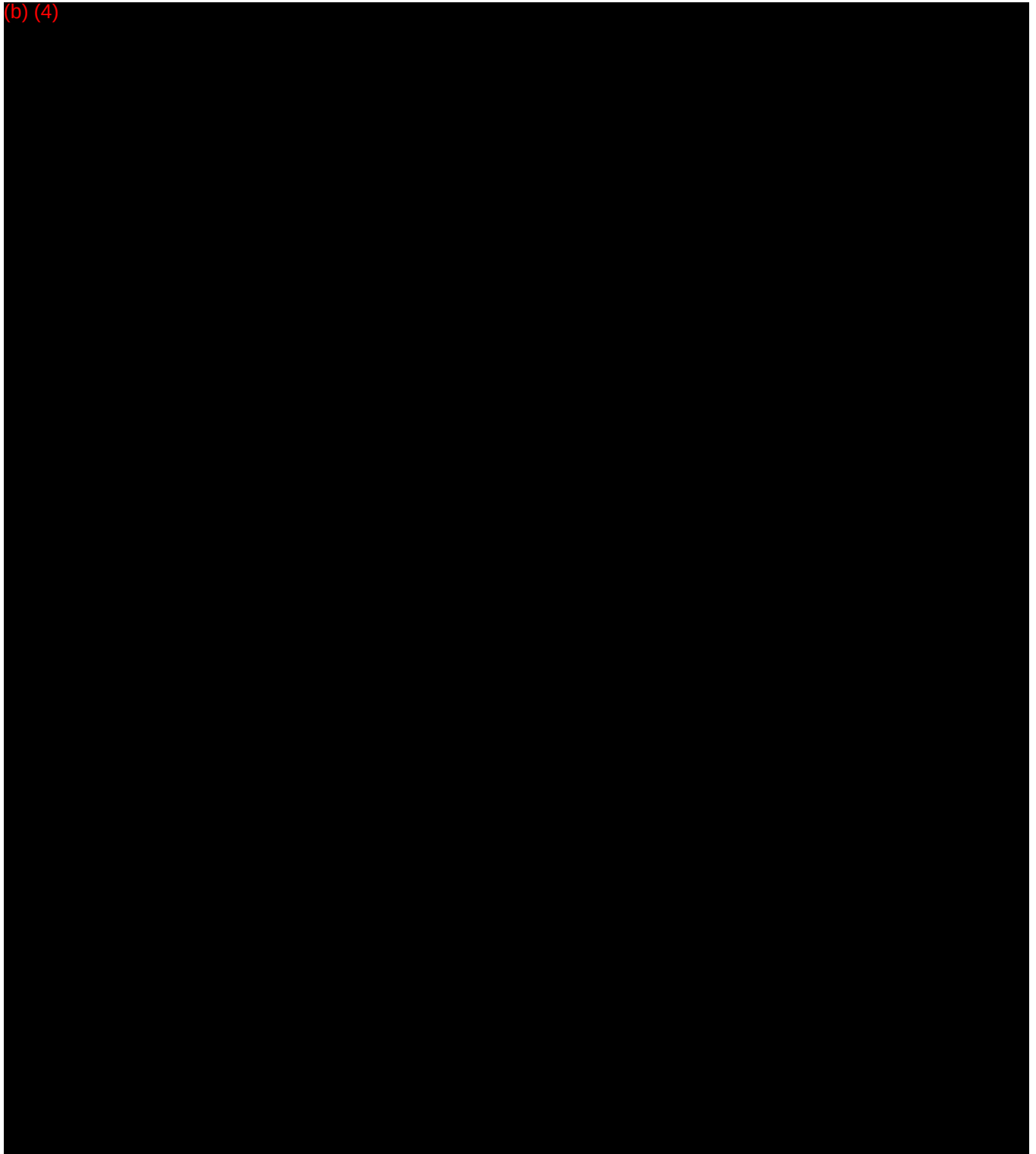
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Pulpdent RMGI Fill

EXHIBIT 3

DEVICE SPECIFICATION, DESCRIPTION, INTENDED USE, FORMULAS

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PULPDENT CORPORATION

510 k Premarket Notification

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Pulpdent RMGI Fill

EXHIBIT 3

DEVICE SPECIFICATION, DESCRIPTION, INTENDED USE, FORMULAS

DESCRIPTION AND INTENDED USE:

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, *RMGI Fill* 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 Fill* is a paste-paste formulation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.

FORMULAS			
BASE – PART A			
FUNCTION	CHEMICAL NAME	CAS / CI No.	Quantity (%) ¹

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510 k Premarket Notification

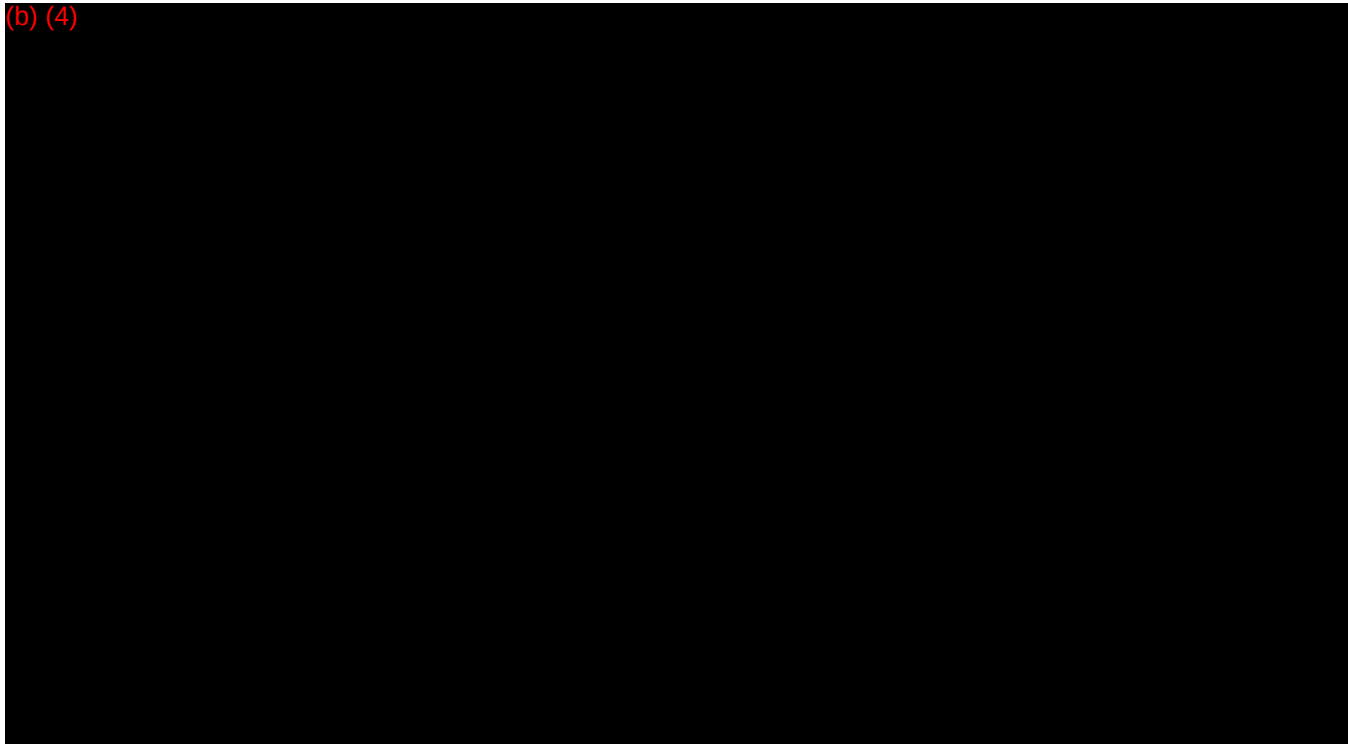
008_Device Specification and Description.docx

Pulpdent RMGI Fill

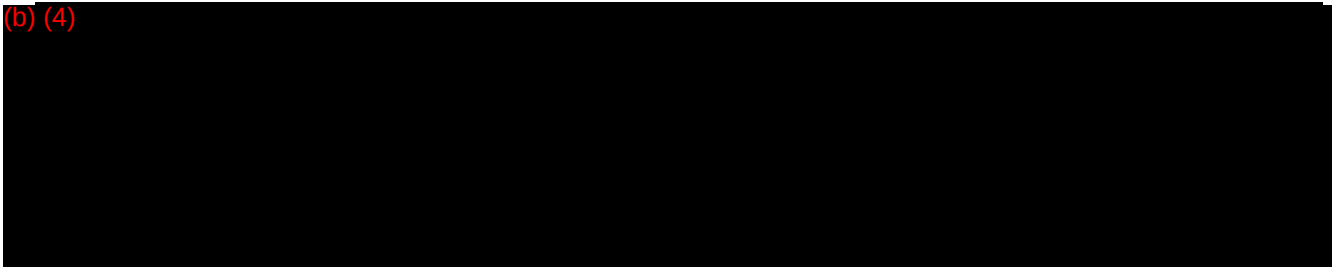
EXHIBIT 3

DEVICE SPECIFICATION, DESCRIPTION, INTENDED USE, FORMULAS

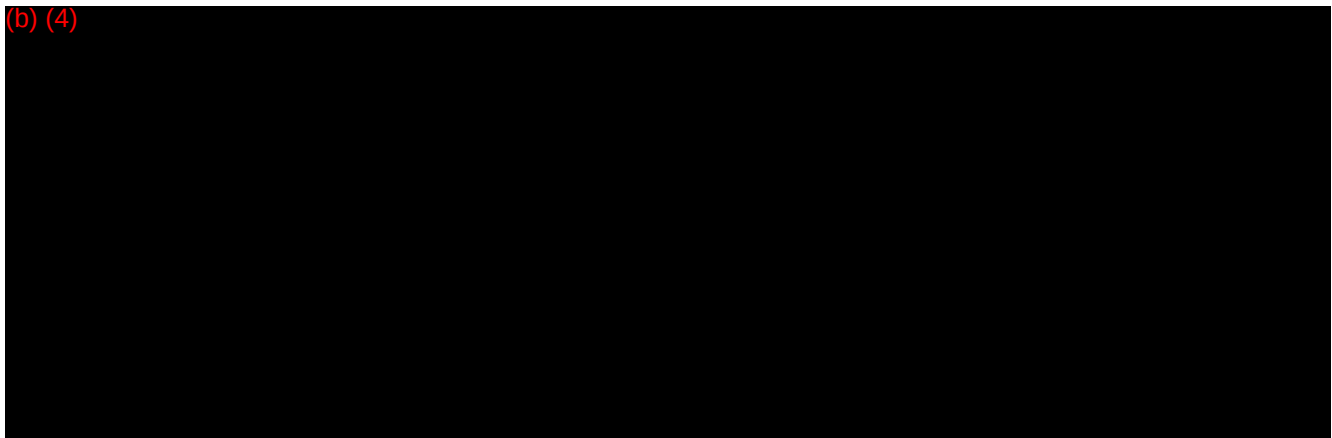
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¹ All quantities $\pm 10\%$

EXHIBIT 4
SUBSTANTIAL EQUIVALENCE DISCUSSION

COMPARISON WITH PREDICATE PRODUCTS

Product	Description	Intended Use	Composition
Pulpdent RMGI Fill	Dual-cure, resin-modified glass ionomer in two pastes	Dental restorative/filling material	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; aluminoflurosilicate ionomer glass, silica, oxidizing agents.
<i>Pulpdent</i> RMGI Low Viscosity K123265	Dual-cure, 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.
<i>3M Espe</i> Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Silane-treated glass, zirconia and silica; ionomer glass; Bis-GMA; PEGDMA; HEMA; TEGDMA. Part B: Silane-treated ceramic; co-polymer of acrylic and itaconic acids; HEMA; water.
GC Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminoflurosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate

EXHIBIT 4

SUBSTANTIAL EQUIVALENCE DISCUSSION

PHYSICAL AND MECHANICAL PROPERTIES

	PULPDENT RMGI Fill	<i>PULPDENT RMGI Low Viscosity (light-cure)</i>	<i>3M ESPE Ketac Nano</i>	<i>GC Fuji Filling LC</i>
Compressive Strength (MPa)	280	239	236	165
Flexural Strength (MPa)	102	88.0	35	28
Flexural Modulus (GPa)	4.3		5.4	12.3
Diametral Tensile Strength (MPa)	42.0	36	32	15
Shear Bond Strength (MPa) <i>Composite to RMGI Fill</i>	28			
Polymerization Shrinkage	1.7%			

CONCLUSION

From the comparisons and bench testing in the two preceding tables, it can be concluded that *Pulpdent RMGI Fill* is substantially equivalent in design, composition, performance and intended use to the predicate products. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3275. Two of the predicate products have been used by dental professionals for about eight years.

PROPOSED LABELING FOR RMGI FILL

Draft Syringe Label

<u>PULPDENT RMGI Fill</u>	Rx only
Part A – Light sensitive	CE 0459
Resin-modified glass ionomer restorative	xx grams
Lot Number: year-month-day	Expiration date: year-month
PULPDENT CORPORATION	
80 Oakland Street, Watertown, Massachusetts 02472 USA	

<u>PULPDENT RMGI Fill</u>	Rx only
Part B	CE 0459
Resin-modified glass ionomer restorative	xx grams
Lot Number: year-month-day	Expiration date: year-month
PULPDENT CORPORATION	
80 Oakland Street, Watertown, Massachusetts 02472 USA	

Draft Outer Package

<u>PULPDENT RMGI Fill</u>	Rx only
Resin-modified glass ionomer for use as a dental restorative	
Triple Cure • Fluoride Releasing • Hydrophilic • Radiopaque	
Contents: 1 xx gram automix syringe RMGI Fill, xx mixing tips, Instructions for Use, MSDS	
ISO 9917-2 Class 3 Restorative	
5°C  	
 PULPDENT CORPORATION	
80 Oakland Street, Watertown, Massachusetts 02472 USA • www.pulpdent.com • Pulpdent@pulpdent.com	

Draft Control Label for Outer Package

REF xxxxxxxx	LOT year-month-day	 20xx-month	Bar code
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PROPOSED LABELING FOR RMGI FILL

INSTRUCTIONS FOR PROPER USE, STORAGE AND HANDLING

Pulpdent RMGI Fill

Rx only

Resin-Modified Glass Ionomer Restorative

Triple Cure • Fluoride Releasing • Hydrophilic • Radiopaque

PRODUCT DESCRIPTION

RMGI Fill is a triple cure formula with three setting mechanisms: light cure, self-cure resin chemistry, and self-cure glass ionomer reaction. The material contains no Bisphenol A, no BisGMA and no BPA derivatives.

INDICATIONS

Recommended as a bioactive filling material for pits, root surface cavities, and Class I, II, III and V, restorations where there is no pulpal involvement.

CONTRAINDICATIONS

Not indicated for direct placement on the exposed pulp. See instructions for use.

PHYSICAL PROPERTIES

Light cure setting time: 20 seconds in increments of 2mm

Self-cure setting time at 37° C: 2 minutes, 20 seconds (intraoral)

Self-cure setting time at 20° C: 3 minutes, 30 seconds (extra-oral)

Percentage filler by weight: 54%

Percentage reactive glass filler by weight: >42

Fluoride release 1 day: 230 ppm

Fluoride release 28 days (cumulative): 940 ppm

Flexural strength: 102 MPa/ 14,790 Psi

Flexural modulus: 4.3 GPa

Compressive strength: 280 MPa / 40,600 Psi

Diametral tensile strength: 42 MPa /6090 Psi

Water sorption (1 week): 1.65%

HOW TO USE THE AUTOMIX SYRINGE

- ♦ Remove cap. If necessary bleed the syringe so that base and catalyst are at the orifice of the syringe barrels. Place a mixing tip on the automix syringe.
- ♦ To ensure an even mix of base and catalyst, dispense 1-2 mm onto a pad and discard this material.
- ♦ Dispense evenly mixed RMGI Fill directly onto the tooth.
- ♦ Discard mixing tip. Recap syringe. Do not cross-contaminate base and catalyst.

SLIGHTLY MOIST SURFACES DEFINED

Slightly moist tooth surfaces exhibit neither dryness nor pooling of water. Lightly dry and remove excess water with compressed air or a cotton pellet. Tooth surfaces should be shiny or glossy. Overly wet surfaces will result in decreased bond strength.

PROPOSED LABELING FOR RMGI FILL

INSTRUCTIONS FOR USE

1. Isolate tooth using rubber dam. Avoid water and saliva contamination during the placement of RMGI Fill.
2. Remove carious dentin, and pre-existing restorations and liner materials from the internal aspects of the preparation. Clean, rinse, and lightly dry the preparation leaving the surfaces slightly moist. Do not over dry.
3. In the event of a pulpal exposure, place Pulpdent Paste or Multi-Cal in accordance with the instructions for use. Place a thin layer of RMGI-Fill over the calcium hydroxide paste as a hard base. Light cure or allow to self-cure.
4. Etch entire preparation (enamel, dentin and cementum) with Pulpdent Etch-Rite Etching Gel for 15-20 seconds.
5. Place a mix tip on the RMGI-Fill syringe. To ensure an even mix of base and catalyst, dispense 1-2 mm of material onto a mixing pad and discard this material. Apply a thin layer (2 mm or less) of RMGI-Fill to the prepared surfaces of the cavity and spread the material evenly using a suitable instrument.
6. Closed Sandwich Technique: Do not extend the material over the enamel margins for the closed sandwich technique. Etch remaining enamel cavo surface for 15 seconds, rinse and dry. Apply DenTASTIC UNO or your preferred adhesive bonding agent in accordance with the instructions for use. Place composite and finish restoration.
7. Open Sandwich Technique: extend RMGI-Fill to the enamel cavo surface margin.
8. Add RMGI-Fill Restorative in 2 mm increments, as indicated, curing between each layer.
9. Light Cure for 20 seconds. Intraoral self-cure setting time is 2 minutes 20 seconds.

STORAGE AND HANDLING

- ♦ Discard used mixing tips; replace the original sealing cap onto syringe. Use a new tip for each patient.
- ♦ Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature (>80°F/27°C, <40°F/5°C), contamination between parts and sources of ignition.
- ♦ Shelf life of unopened product: 2 years from date of manufacture.
- ♦ Re-cap immediately after use.

Note: Multi-dose syringes should either be encased in a fresh protective barrier for each patient or cleaned and disinfected between patients, as appropriate.

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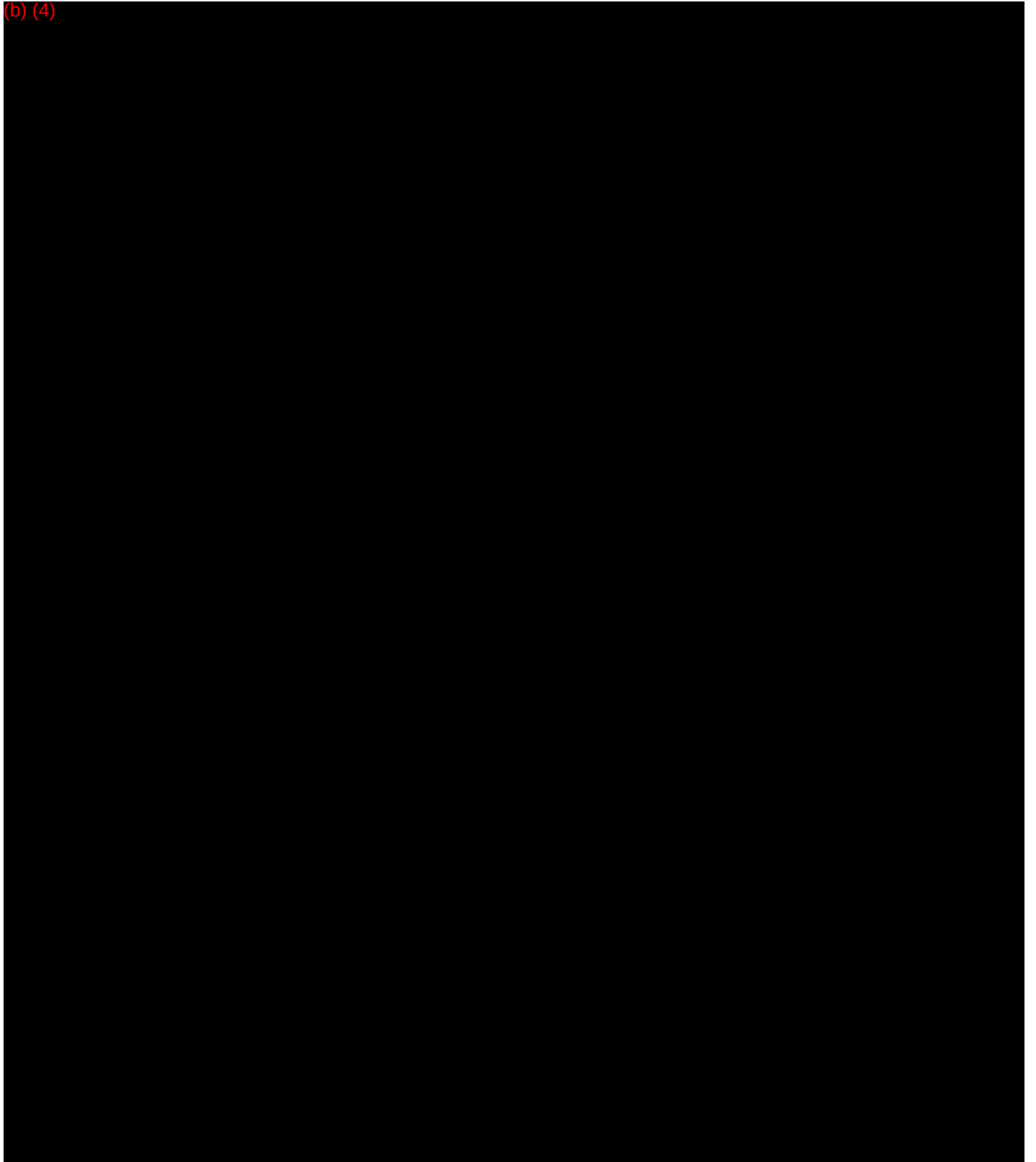
80 Oakland Street, Watertown, MA 02472 USA

Tel: (800) 343-4342 / (617) 926-6666 / Fax: (617) 926-6262

PROPOSED LABELING FOR RMGI FILL

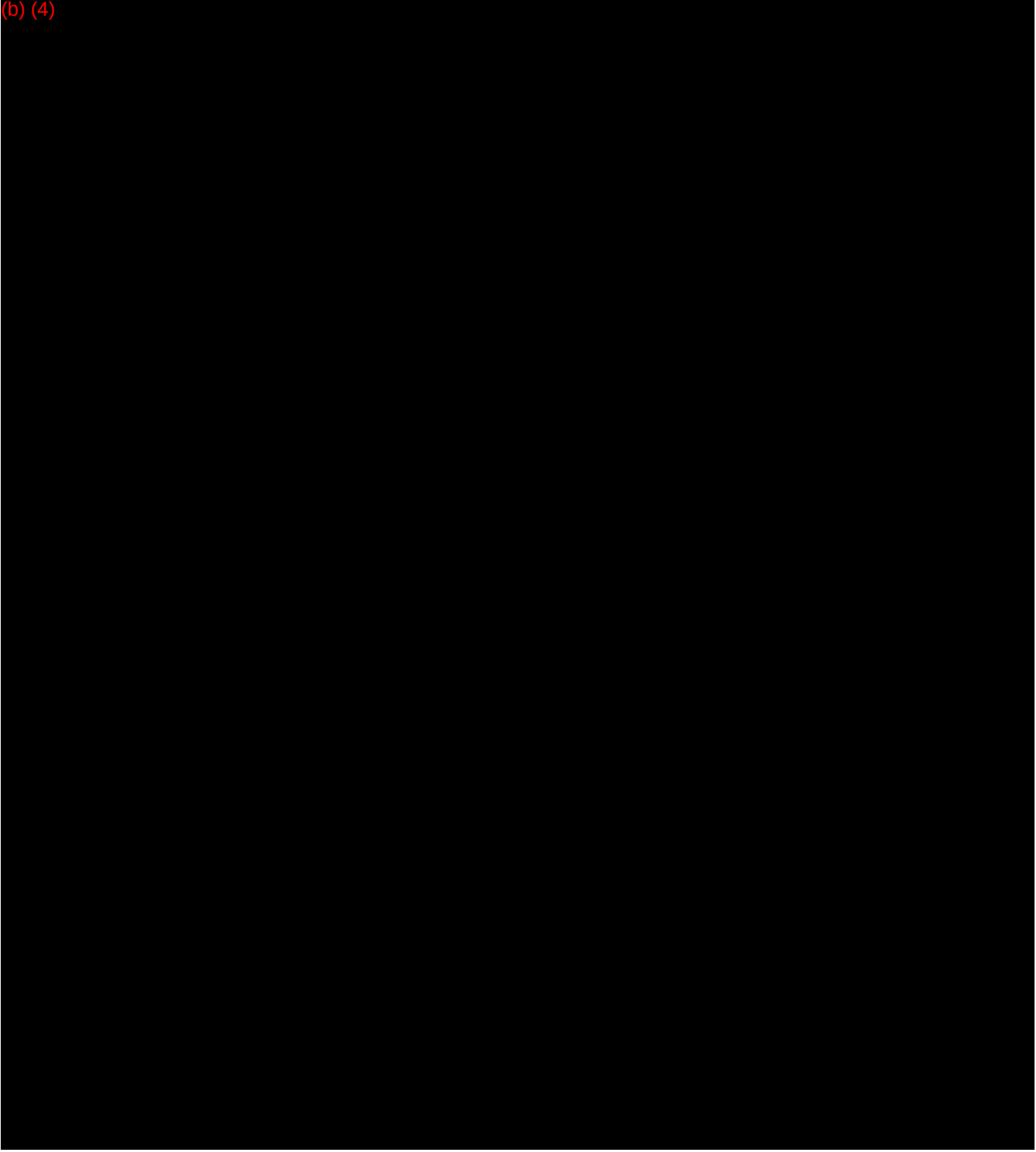
MATERIAL SAFETY DATA SHEET

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PROPOSED LABELING FOR RMGI FILL

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PROPOSED LABELING FOR RMGI FILL

Proposed Advertising

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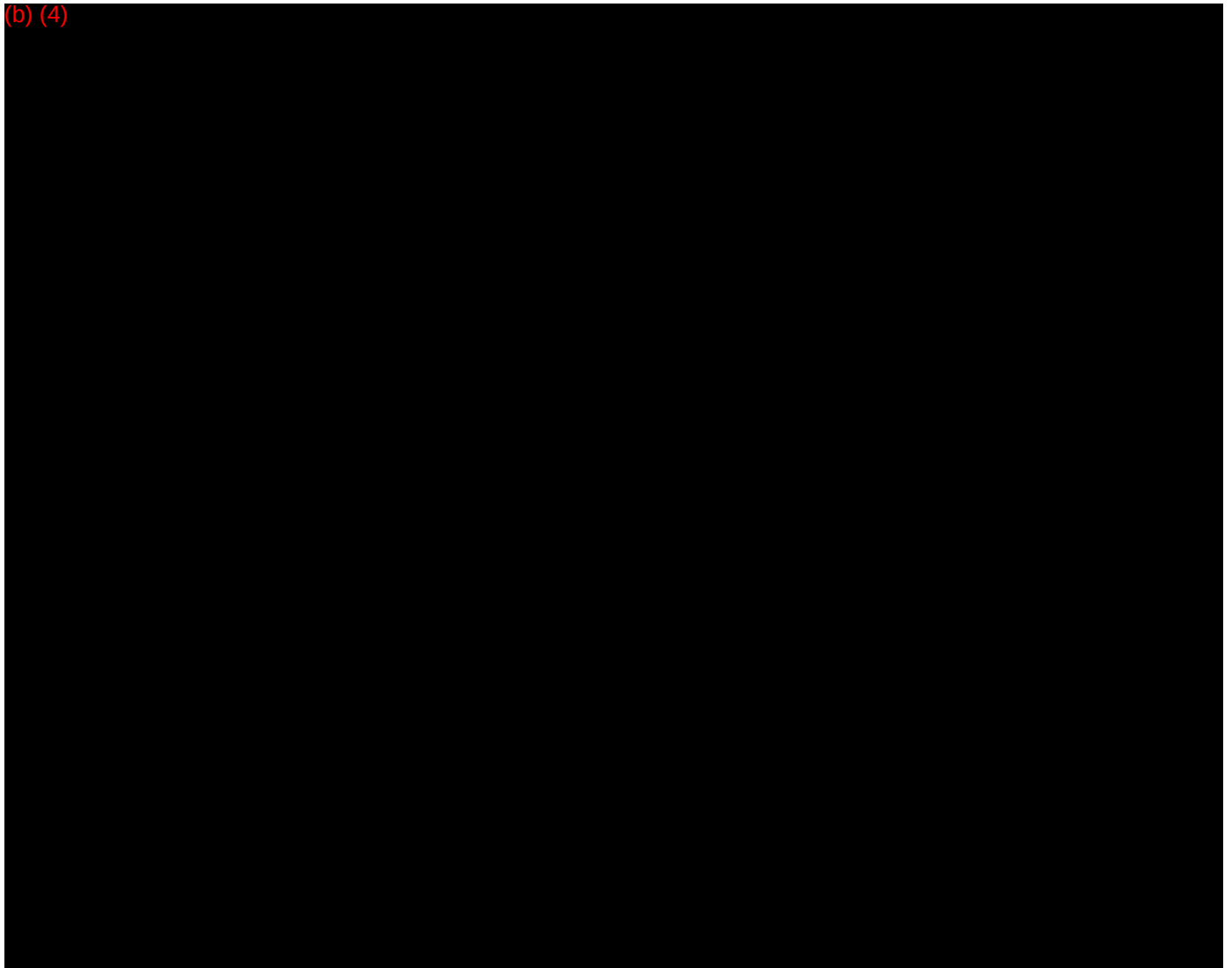


EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

**DESCRIPTION AND INTENDED
USE:**

PATIENT CONTACT

Nature of contact

**Ratio of size of contact area to
body size**

Duration of contact

Chemical nature of the product

Physical nature of the product

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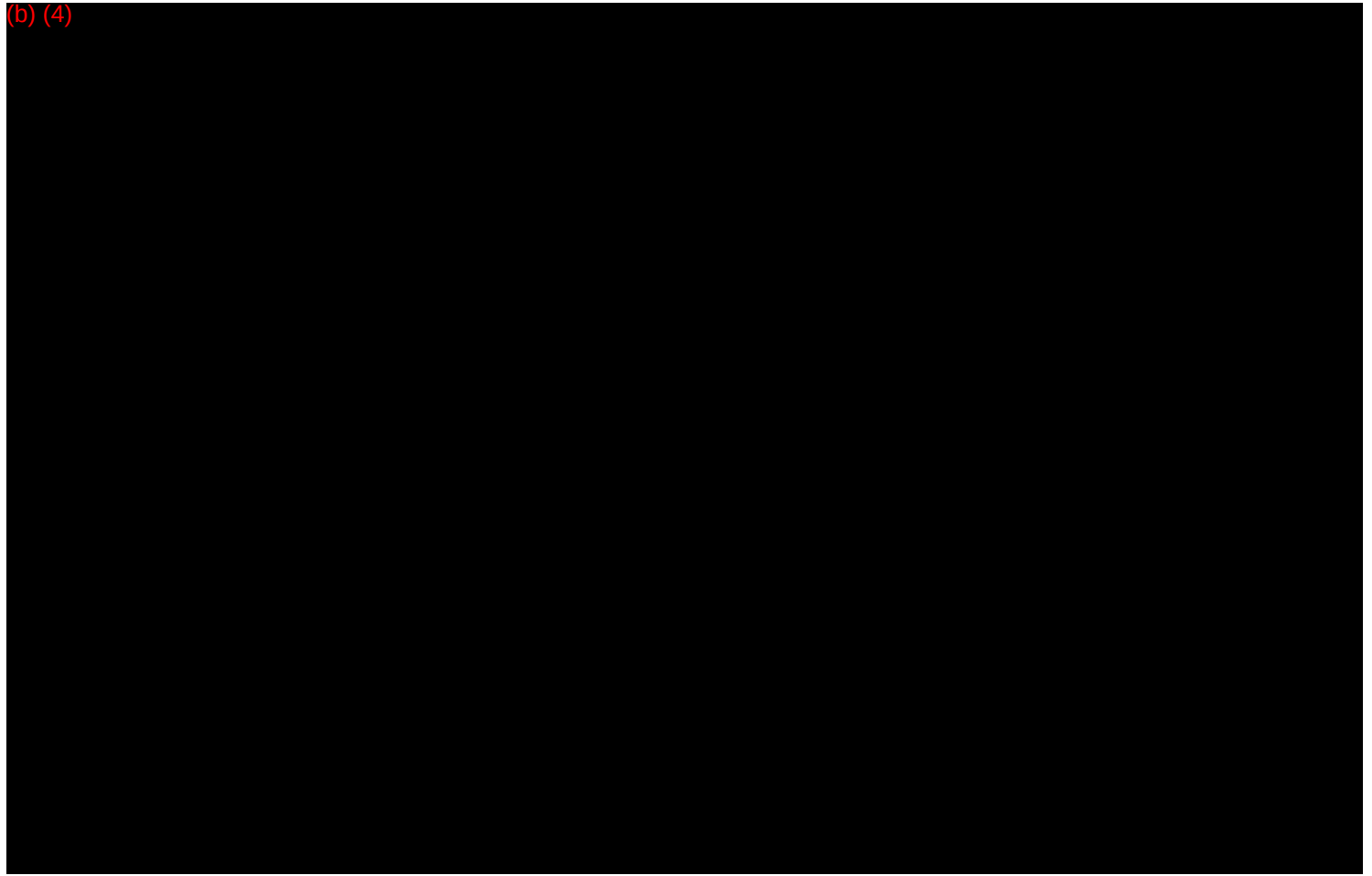


EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

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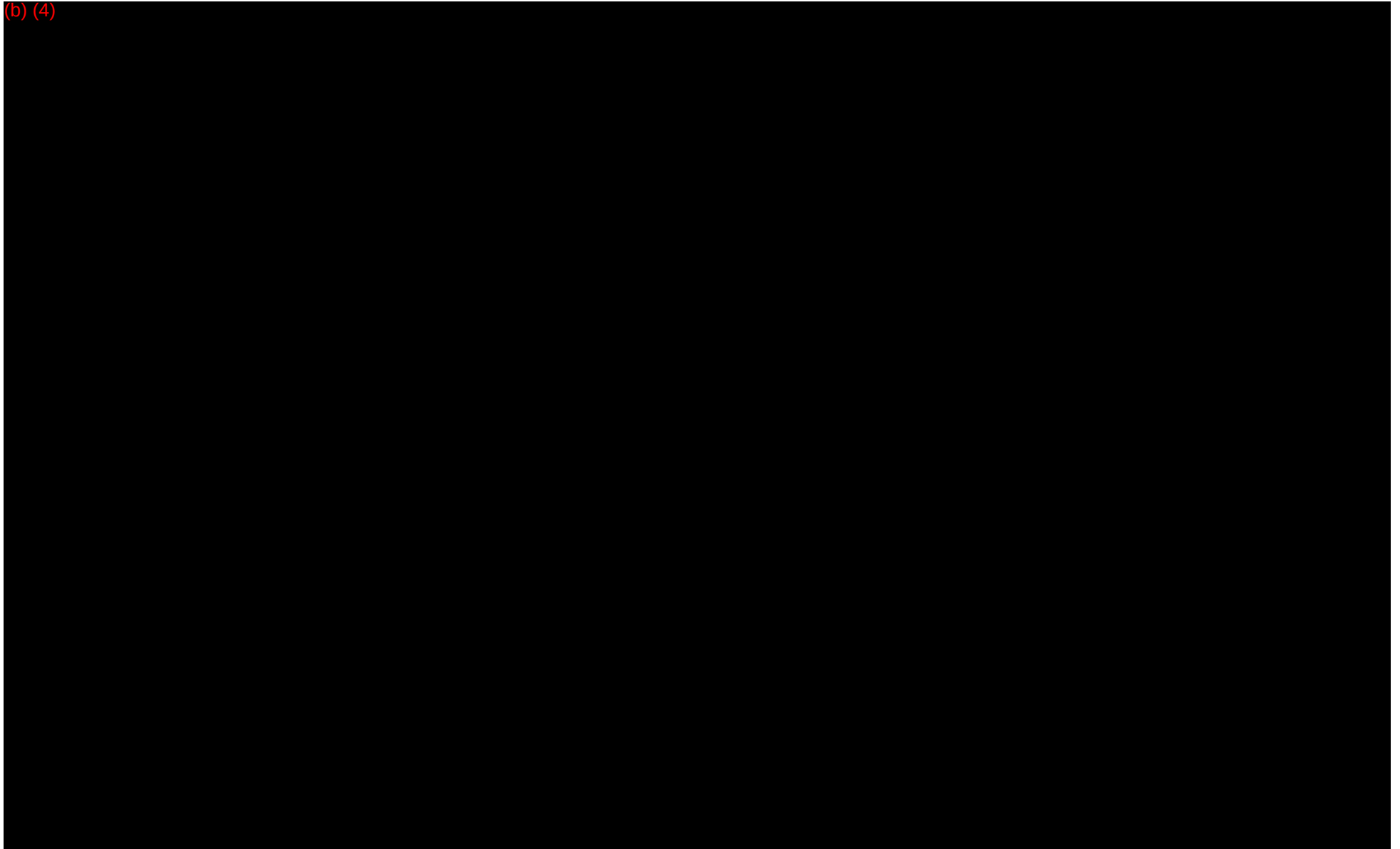


EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

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EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

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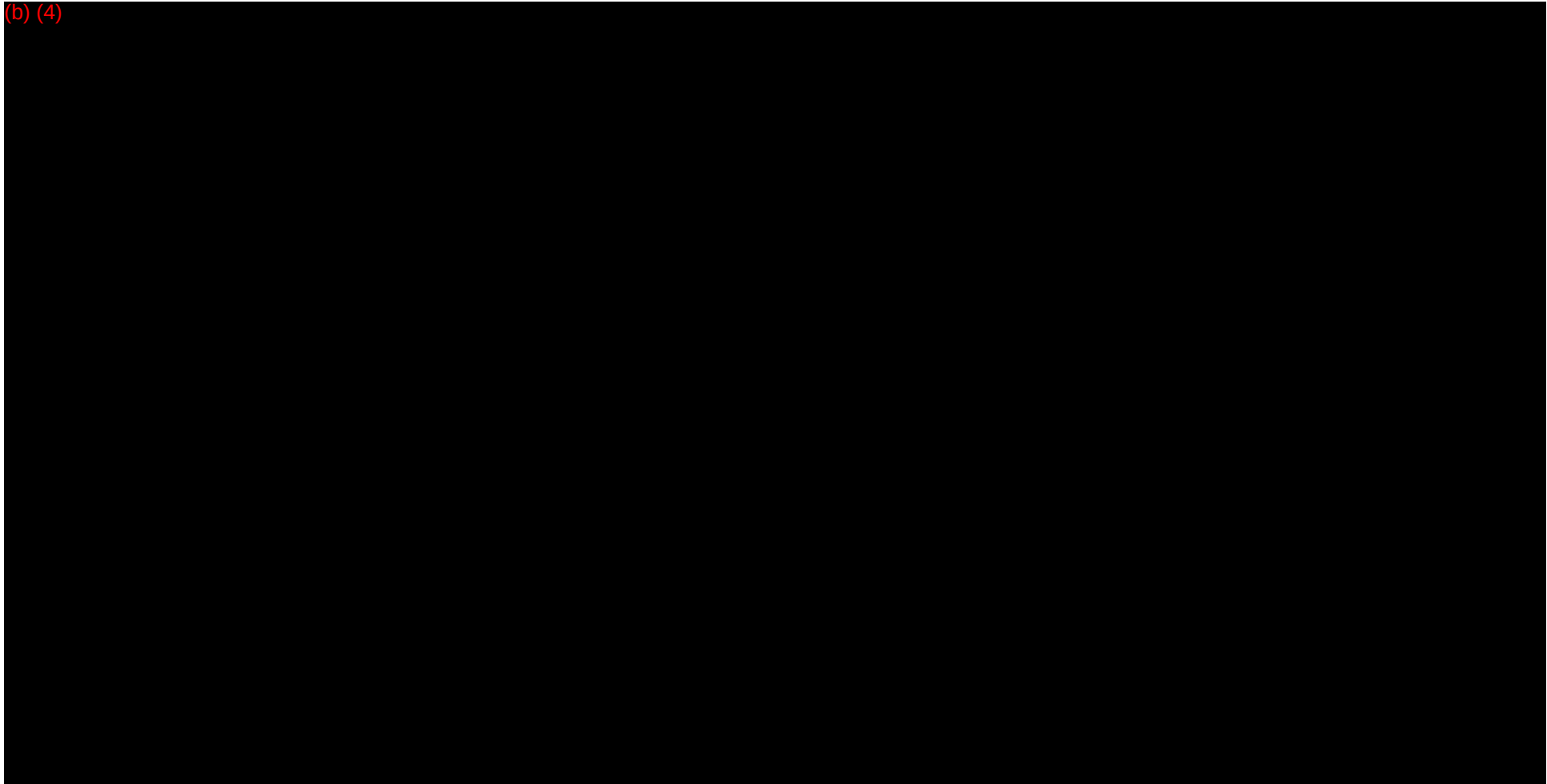


EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

BIOCOMPATIBILITY TESTING:

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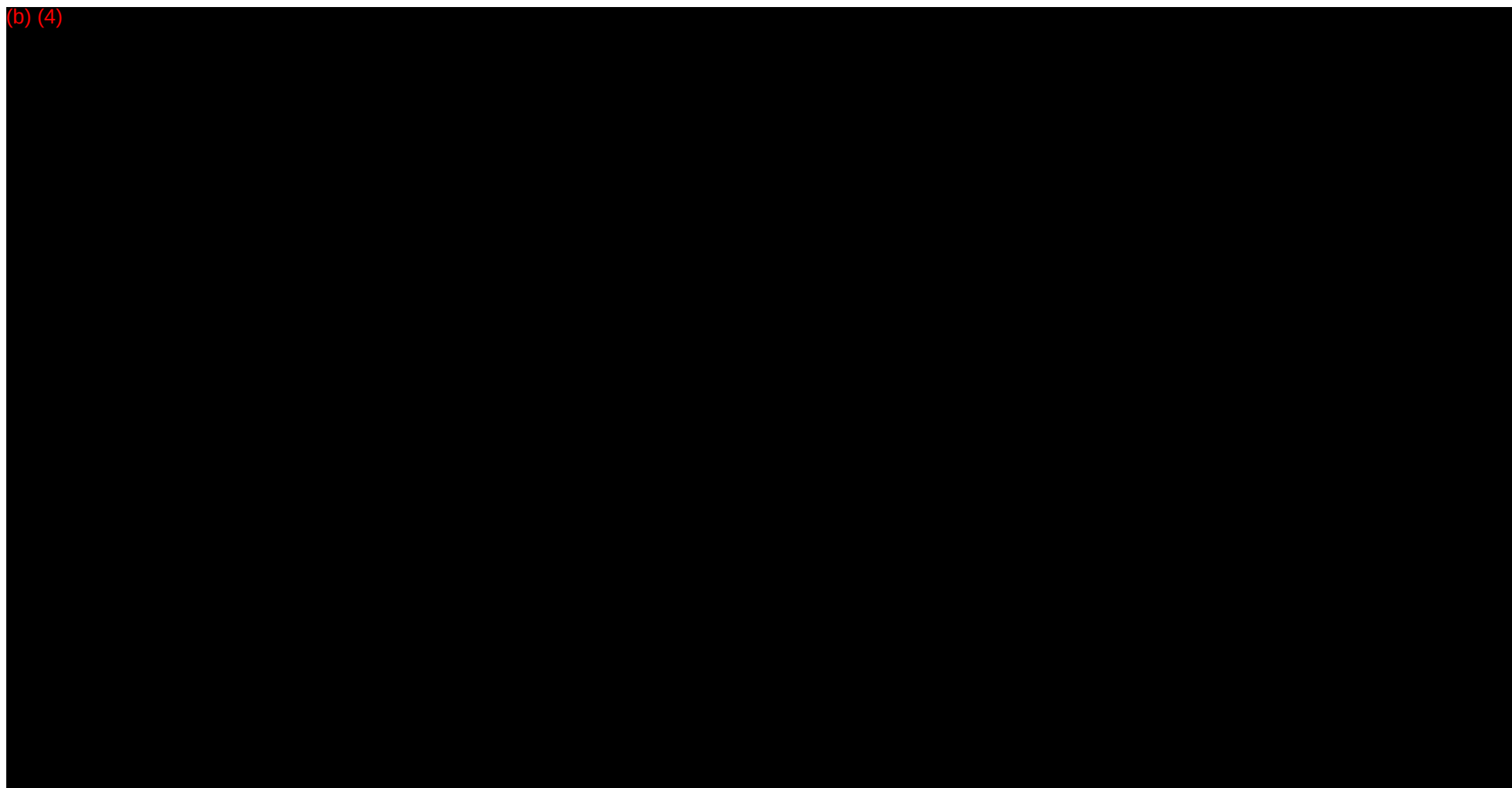


EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

BIOCOMPATIBILITY REFERENCES IN LIEU OF TESTING:

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EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

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18

BIOCOMPATIBILITY OF PACKAGING AND APPLICATOR TIPS

(b) (4)

CONCLUSION:

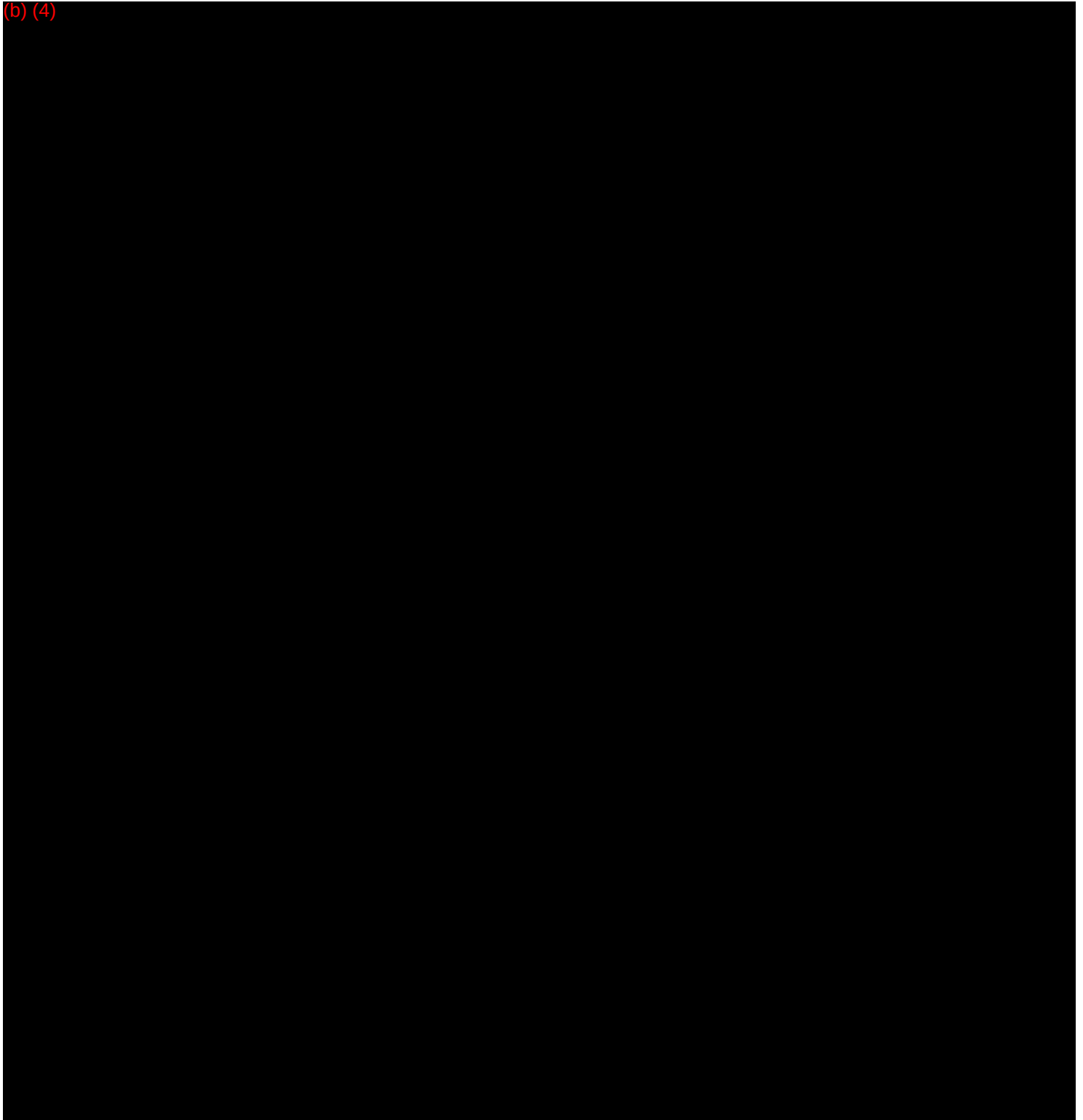
From the review of chemical components, the biocompatibility testing performed by Dr. Pamiejer and found in the References listed above, it has been determined that the biocompatibility of RMGI Fill is Acceptable.

EXHIBIT 6 - BIOCOMPATIBILITY EVALUATION REPORT: *RMGI Fill*

NOTE: Material Safety Data Sheets for each component material are located on the disc in pdf form.

EXHIBIT 7 - PERFORMANCE TESTING – BENCH

(b) (4)



Usability Evaluation: *RMGI Fill*

BS EN 62366:2008 Documentation of Compliance

Product	<i>RMGI Fill</i>
Product Description	<i>Pulpdent RMGI Fill</i> is a two-paste resin-modified glass ionomer preparation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.
Issue:	Rev. 1
Date:	January 16, 2013
Compiled by:	Marjorie Coté

Pulpdent Corporation**Usability Evaluation: *RMGI Fill***

1 Inputs to the USABILITY SPECIFICATION**1.1 Specification of the INTENDED USE/INTENDED PURPOSE****1.1.1 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, *RMGI Fill* 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 Fill is a paste-paste formulation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.

1.1.2 DEVICE application specification**1.1.2.1 Medical purpose**

RMGI Fill is used by dental professionals as a filling material in dental restorations.

1.1.2.2 PATIENT population

- a) Age: Not relevant
- b) Weight: Not relevant
- c) Health: Not relevant
- d) Nationality: Multiple
- e) Patient state: PATIENT is not the USER, therefore, not relevant unless patient is agitated or uncooperative.

1.1.2.3 Part of body or type of tissue applied to or interacted with

RMGI Fill is applied into or onto tooth structure.

1.1.2.4 Intended OPERATOR

Dental professional, i.e., dentist, hygienist, etc.

1.1.2.5 Application

- a) Environment

General:

- Dental office
- Clinic

Conditions of visibility:

- Applied under usual dental operatory lighting

Pulpdent Corporation

Usability Evaluation: *RMGI Fill*

Physical:

- Normal ambient conditions apply.
- b) Frequency of use:
 - As necessary, depending on clinical situation.
- c) Mobility of patient:
 - Not relevant; applied by dental professional.

1.2 PRIMARY OPERATING FUNCTION

1.2.1 Frequently used functions

- a) Remove cap. If necessary bleed the syringe so that base and catalyst are at the orifice of the syringe barrels. Place a mixing tip on the automix syringe.
- b) To ensure an even mix of base and catalyst, dispense 1-2 mm onto a pad and discard this material.
- c) Dispense evenly mixed RMGI Fill directly onto the tooth (base or liner) or prosthetic restoration (luting agent).*****
- d) Light Cure for 20 seconds. Self-cure setting time is 3.5 minutes
- e) Discard mixing tip. Recap syringe. Do not cross-contaminate base and catalyst.
- f) Finish restoration as indicated.

1.2.2 Functions related to SAFETY

- a) Encase multi-dose auto syringe in plastic barrier to prevent cross-contamination between patients.
- b) Use a new mixing tip for each patient.
- c) Give patient or care-giver post-treatment instructions.
- d) Dispose of used mixing tip.

1.3 Risk analysis

1.3.1 INTENDED USE/INTENDED PURPOSE

See 1.1

1.3.2 USER PROFILE

See 1.1.2.4

1.3.3 Things That could go wrong

Sources: Scientific and Clinical Literature, Postmarket Surveillance, Adverse Event Databases, Risk Analysis, etc.

Pulpdent Corporation

Usability Evaluation: *RMGI Fill*

- a) During normal use:
 - Patient may be allergic or sensitized to a component of RMGI Fill.
 - Material may not dispense from automix syringe in the optimum ratio of 1:1.
- b) Use Errors:
 - Using a single mixing tip for more than one patient.
 - Not handling the automix syringe properly.
 - Using an inadequate curing light.
 - Untrained or non-professional personnel using *RMGI Fill* on a patient.
 - Failure to follow Instructions for Use.
 - Failure to give patient or care-giver post treatment instructions.
- c) Environment
 - RMGI Fill syringe is stored above or below the recommended temperatures.
 - RMGI Fill syringe is left under intense light for long periods of time.
- d) Patient
 - Patient is uncooperative or agitated.
 - Patient does not follow post-treatment instructions.
- e) Reading:
 - Practitioner does not read Instructions for Use.
- f) Hygiene:
 - Failure to cover automix syringe with plastic barrier.
 - Using a mixing tip for more than one patient.

1.3.4 Task requirements

- a) Opening kit, removing syringe and mixing tips, and finding Instruction for Use are uncomplicated and easy.
- b) Instructions for Use are clear and readable.
- c) Attachment and priming of mixing tip for optimum ratio of parts is straightforward.
- d) Material dispenses without undue effort.
- e) Material cures within claimed time.

1.3.5 The context of use

See 1.1.2.5

1.3.6 Information on HAZARDS known for existing device

- a) Patient may be allergic or sensitized to a component of RMGI Fill.

Usability Evaluation: *RMGI Fill*

- b) If a bubble is present in one side of the automix syringe, the material may not dispense in the optimum ratio of 1:1.
- c) If the mixing tip is used for more than one patient, there may be cross infection.
- d) If the automix syringe is not handled properly, material may polymerize from cross-contamination between parts and be unusable.
- e) If automix syringe is not handled properly, the material may not dispense in the optimum ratio of 1:1.
- f) If curing light is not adequate, curing time will be affected.
- g) If *RMGI Fill* is used by untrained or non-professional personnel, the restoration may fail.
- h) If the practitioner fails to follow Instructions for Use, the restoration may fail.
- j) If the practitioner fails to give patient or care-giver post treatment instructions, the restoration may fail.
- k) If the patient fails to follow post-treatment instructions, the restoration may fail.

1.3.7 Resulting HAZARDOUS SITUATIONS and HARMS

- a) Patient may be allergic or sensitized to a component of *RMGI Fill* → allergic reaction.
- b) Material does not dispense in the optimum ratio of 1:1 → may not set properly and/or the restoration may fail.
- c) If curing light does not cure material properly → restoration may fail.
- d) Mixing tip is used for more than one patient → cross infection.
- e) Automix syringe is not handled properly → material may polymerize from cross contamination between parts and be unusable.
- f) Automix syringe is not handled properly → the material may not dispense in the optimum ratio of 1:1 → may not set properly and/or the restoration may fail.
- g) *RMGI Fill* is used by untrained, non-professional personnel → restoration may fail.
- h) Practitioner fails to follow Instructions for Use → restoration may fail.
- i) Practitioner fails to give patient or care-giver post treatment instructions → restoration may fail.

1.3.8 Preliminary review of the USER INTERFACE concept

- a) Open kit. Remove syringe and mixing tips, finding Instruction for Use.
 - Easy to open kit and remove contents.Conclusion: No issues
- b) Remove cap. If necessary bleed the syringe so that base and catalyst are at the orifice of the syringe barrels. Place a mixing tip on the automix syringe.
 - Cap unscrews easily. Bleeding the syringe is straightforward.
 - Mixing tip attaches without any problem.

Usability Evaluation: *RMGI Fill*

Conclusion: No issues

c) Priming of automix tip by dispensing 1-2 cm of material.

- Sold to and used by dental professionals only.
- Detailed Instructions for Use
- Standard procedure for automix syringe

Conclusion: No issues.

d) Dispensing of material onto tooth or restoration.

- Sold to and used by dental professionals only.
- Detailed Instructions for Use
- Easy to expel material from syringe and to accurately place it.

Conclusion: No issues

e) Curing RMGI Fill

- Light cures in 20 seconds with most lights
- Self-cures in 3.5 minutes.

Conclusion: No issues

f) Reading Instructions for Use and Labeling

- Font and lines clearly legible
- Instructions for Use and MSDS included in kit.
- Product labeling on outer package and on automix syringes. Bags of tips are also labeled.

g) Discard mixing tip and syringe cover. Recap syringe.

Conclusion: No issues

h) Patient involvement

- Only patient involvement during procedure is to be cooperative.
- After procedure, patient is to follow instructions for post-treatment care.

Conclusion: No issues.

Conclusion: No issues

2 USABILITY SPECIFICATION

2.1 General

a) MEDICAL DEVICE

RMGI Fill

Usability Evaluation: *RMGI Fill*

- b) Basis:
- Intended use, see 1.1
 - Possible use errors, see 1.3.3
 - Hazardous situations or harms related to use, see 1.3.7.
 - Context of use
 - o Dental professional uses RMGI Fill as one step in a restoration being performed in a dental operatory.
 - Preliminary use scenarios
 - o Dental professional uses RMGI Fill as a filling material in a dental restorations.

2.2 USE SCENARIOS

Worst case scenarios to provide a basis for validation

- a) Dental professional fails to follow Instructions for Use
- Optimum 1:1 ratio of Part A and Part B is not dispensed and material fails to set.
 - Optimum 1:1 ratio of Part A and Part B is not dispensed and restoration fails.
 - Cross-contamination of parts results in polymerization of syringe contents.
- b) Dental professional fails to take cross-infection precautions.
- Patients and practitioners may become infected from multi-dose syringe.
- c) Patient is uncooperative
- Restoration may fail

2.3 USER actions related to PRIMARY OPERATING FUNCTIONS

- a) Read Instructions for Use
- b) Prepare and prime syringe.
- c) Attach mixing tip and dispense 1-2 cm of material; discard.
- d) Prepare tooth and dispense material.
- e) Light cure or allow material to self-cure.
- f) Finish restoration
- g) Give patient post-treatment instructions.
- h) Dispose of used mixing tip and syringe barrier.

2.4 USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS

- a) Read Instructions for Use
- Font and lines are clear and legible
 - Instructions for Use are written using terms and language that are familiar to professional dental practitioners.

Usability Evaluation: *RMGI Fill*

- Instructions for Use are included in each kit, available online and from Customer Service.
- b) Prepare and prime syringe
 - Remove syringe cap
 - Bleed the syringe so that base and catalyst are at the orifice of the syringe barrels.
- c) Attach mixing tip and dispense 1-2 cm of material; discard.
 - Tips is easy to attach
 - Material extrudes from the syringe without undue force.
- e) Prepare tooth and dispense material
 - Restorations are only undertaken by dental professionals who have been trained to perform them.
 - RMGI Fill is a prescription medical device sold only to dental professionals.
 - RMGI Fill dispenses easily and precisely.
- f) Finish restoration
 - Restorations are only undertaken by dental professionals who have been trained to perform them.
 - RMGI Fill is a prescription medical device sold only to dental professionals.
- g) Give patient post-treatment instructions.
- h) Dispose of used mixing tip and syringe barrier
 - Dental procedures are only undertaken by dental professionals who have been trained in avoiding cross-infection.

2.5 USER INTERFACE requirements for those USE SCENARIOS that are most frequent or related to SAFETY

- a) The procedure for using an automix syringe filled with RMGI Fill shall be straightforward and readily accomplished after reading the accompanying Instructions for Use.
 - Prepare and prime syringe.
 - Attach mixing tip and dispense 1-2 cm of material; discard.
 - Prepare tooth and dispense material.
 - Light cure or allow material to self-cure.
 - Finish restoration
 - Give patient post-treatment instructions.
 - Dispose of used mixing tip and syringe barrier.
- b) Text: English for the present; other languages to follow.
- c) Font size 8 pt Arial minimum
- d) Symbols to be intuitive for intended users

Usability Evaluation: *RMGI Fill*

2.6 Requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by USER

- a) Reading Instructions for Use:
 - Instructions for Use are written using terms and language that are familiar to professional dental practitioners.
 - Additional requirements: develop foreign language instructions or diagrams for those who do not read English.
- b) Prepare and prime syringe.
 - Procedure is familiar to dental practitioners
 - No additional requirements
- c) Attach mixing tip and dispense 1-2 cm of material; discard.
 - No additional requirements
- d) Prepare tooth and dispense material.
 - Restorations are only undertaken by dental professionals who have been trained to perform them.
 - No additional requirements
- e) Light cure or allow material to self-cure.
 - Check curing light output
 - Standard methods for curing dental materials.
 - Restorations are only undertaken by dental professionals who have been trained to perform them.
 - No additional requirements
- f) Finish restoration
 - Restorations are only undertaken by dental professionals who have been trained to perform them.
 - No additional requirements
- g) Give patient post-treatment instructions:
 - No additional requirements
- h) Dispose of used mixing tip and syringe barrier.
 - No additional requirements

End of specification.

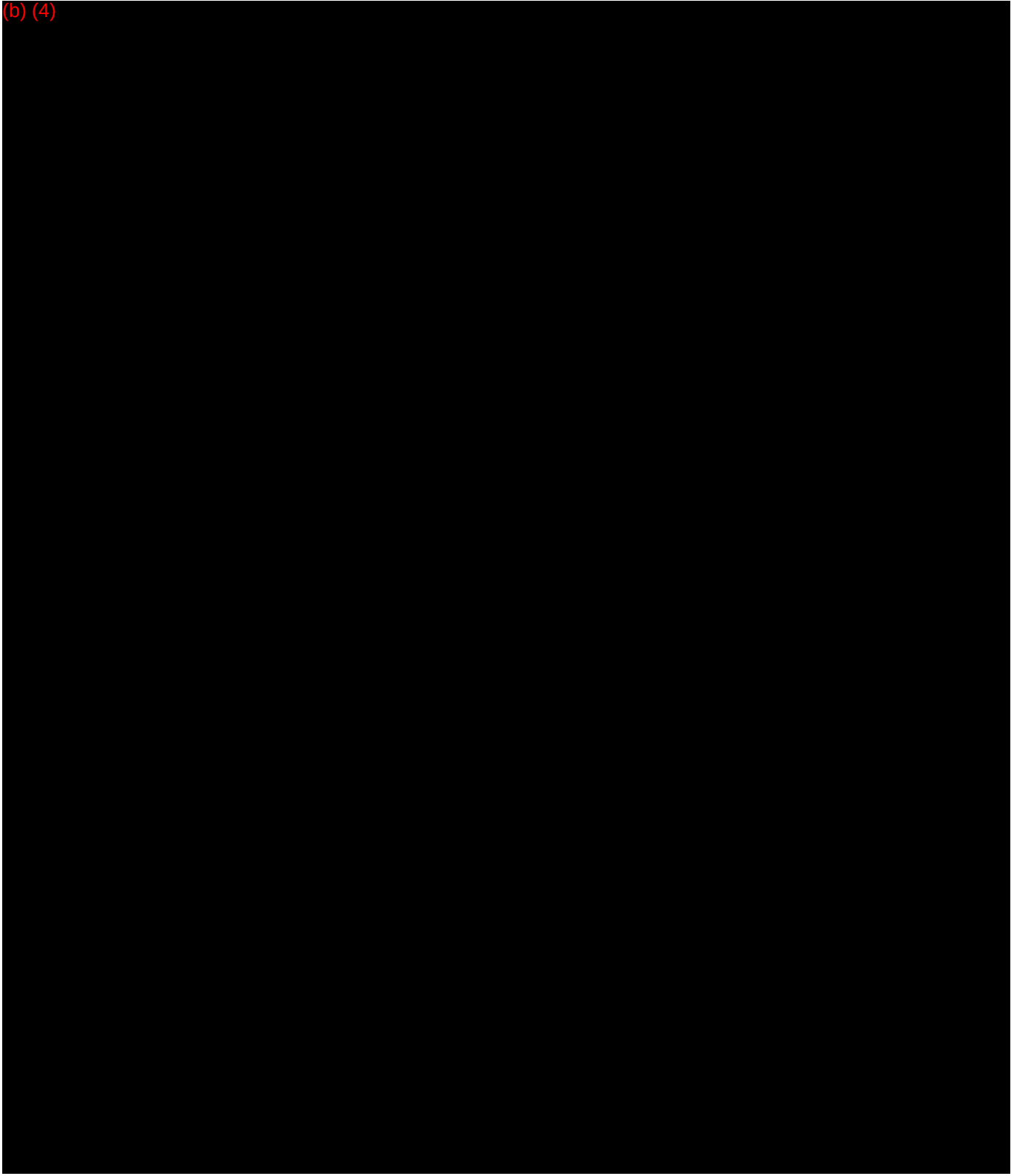
Risk Management File: *RMGI Fill*

(b) (4)



FINAL REPORT

(b) (4)



FINAL REPORT

(b) (4)



* * * COMMUNICATION RESULT REPORT (APR. 3. 2013 11:02AM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : E MODE	APR. 3. 2013 10:55AM OPTION	ADDRESS	RESULT	PAGE
4175 MEMORY TX		16179266262	OK	3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWERE-2) BUSY
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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.

COVER SHEET MEMORANDUM

From: Reviewer Name Girish Kumar
Subject: 510(k) Number K130223
To: The Record

Please list CTS decision code: SE - Substantially Equivalent

- ☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- ☐ Hold (Additional Information or Telephone Hold)
- ☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e. SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page (<i>Attach IFU</i>)	X	
510(k) Summary or 510(k) Statement (<i>Attach Summary or Statement</i>)	X	
Truthful and Accurate Statement (<i>Must be present for a Final Decision</i>)	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)		X
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or testing, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology	Records processed under FOIA Request # 2016-7450; Released by CDRH on 06-22-2018		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)			×

Regulation Number: 21 CFR.872.3275

Class: II

Product Code: EMA

Additional Product Codes:

Digital Signature Concurrence Table	
(Not all signatures may be required)	
Branch Chief Sign-Off	Andrew I. Steen 2013.03.26 14:43:59 -04'00'
Division Sign-Off	Kwame O. Ulmer S 2013.03.29 13:10:22 -04'00'



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave, White Oak, MD 20993

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K130223

Date: March 26, 2013
To: The Record
From: Girish Kumar, PhD
Office/Division: ODE/DAGRID
510(k) Sponsor: Pulpdent Corporation
Device Name: Pulpdent RMGI Fill
Contact: Mr. Ken Berk
Phone: 617-929-6666
Fax: 617-926-6262
Email: ken@pulpdent.com

RECOMMENDATION : SUBSTANTIALLY EQUIVALENT

Purpose and Submission Summary

The 510(k) holder would like to introduce *Pulpdent RMGI Fill* into interstate commerce.

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 Bis-GMA and no BPA derivatives. *Pulpdent RMGI Fill* is a paste-paste formulation provided in an automix syringe.

Pulpdent RMGI Fill is substantially equivalent (SE) to legally marketed dental cement because the information submitted by Pulpdent Corporation, demonstrates that the device has the same design, similar composition, performance, indication and technological characteristics as legally marketed predicate devices.

Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

Indications for Use

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

The indication of *Pulpdent RMGI Fill* does not differ from that of legally marketed dental cement use as a restorative filling material.

Device Description/Formulation

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			

The purpose of this 510(K) is to introduce a new product to market. No novel features have been introduced.

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 acidbase glass ionomer reaction. It contains no Bisphenol A, no Bis-GMA and no BPA derivatives. *RMGI Fill* is a paste paste formulation provided in an automix syringe that is used by dental professionals as a filling material in dental restorations.

The chemical composition of *Pulpdent RMGI Fill* includes the following:

Reviewer also contacted submitter by email on March 25, 2013, regarding some minor editorial changes in 510(k) summary and Executive Summary. The submitter provided all the answers via email on March 25, 2013. Email communications with the sponsor is attached in the file and uploaded in the DocMan. The submitter has addressed all outstanding issues.

Deficiencies

No deficiencies have been identified.

Labeling

The labeling of *Pulpdent RMGI Fill* has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.801.109.

The Proposed Labeling includes draft syringe label for both part A and Part B, draft outer package of device, draft instructions for use storage and handling.

Draft syringe labels for part A and part B have been provided for *RMGI Fill*. It include the information, as follows: device name, common name, lot number, expiration date, manufacturing date, manufacturer name and contact information, "Rx only symbol" (prescription use), and storage instructions for part A-Light sensitive.

Draft outer package of device have been provided for *RMGI Fill*. It include the information, as follows: device name, common name, lot number, expiration date, manufacturing date, manufacturer name and contact information, "Rx only symbol" (prescription use), and storage instructions like temperature and protection from light symbol.

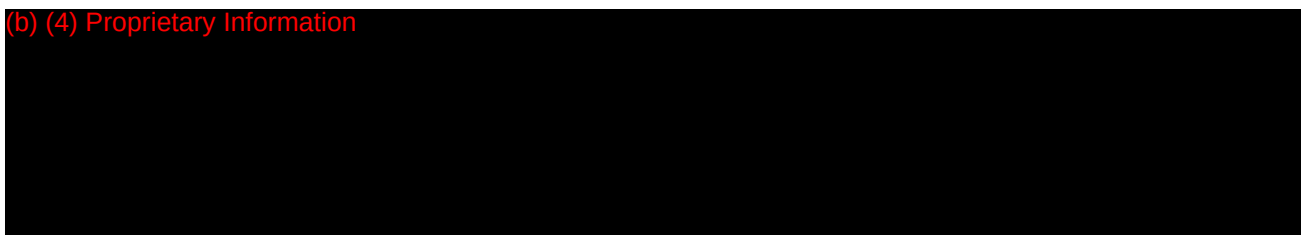
Brochure for *RMGI Fill* was provided which includes draft instructions for use, storage, proper handling, product description, indications, contraindications and physical properties. Instructions for use also include MSDS of the product and proposed advertising. No unsubstantiated claims are purported.

Sterilization/Shelf Life/Reuse:

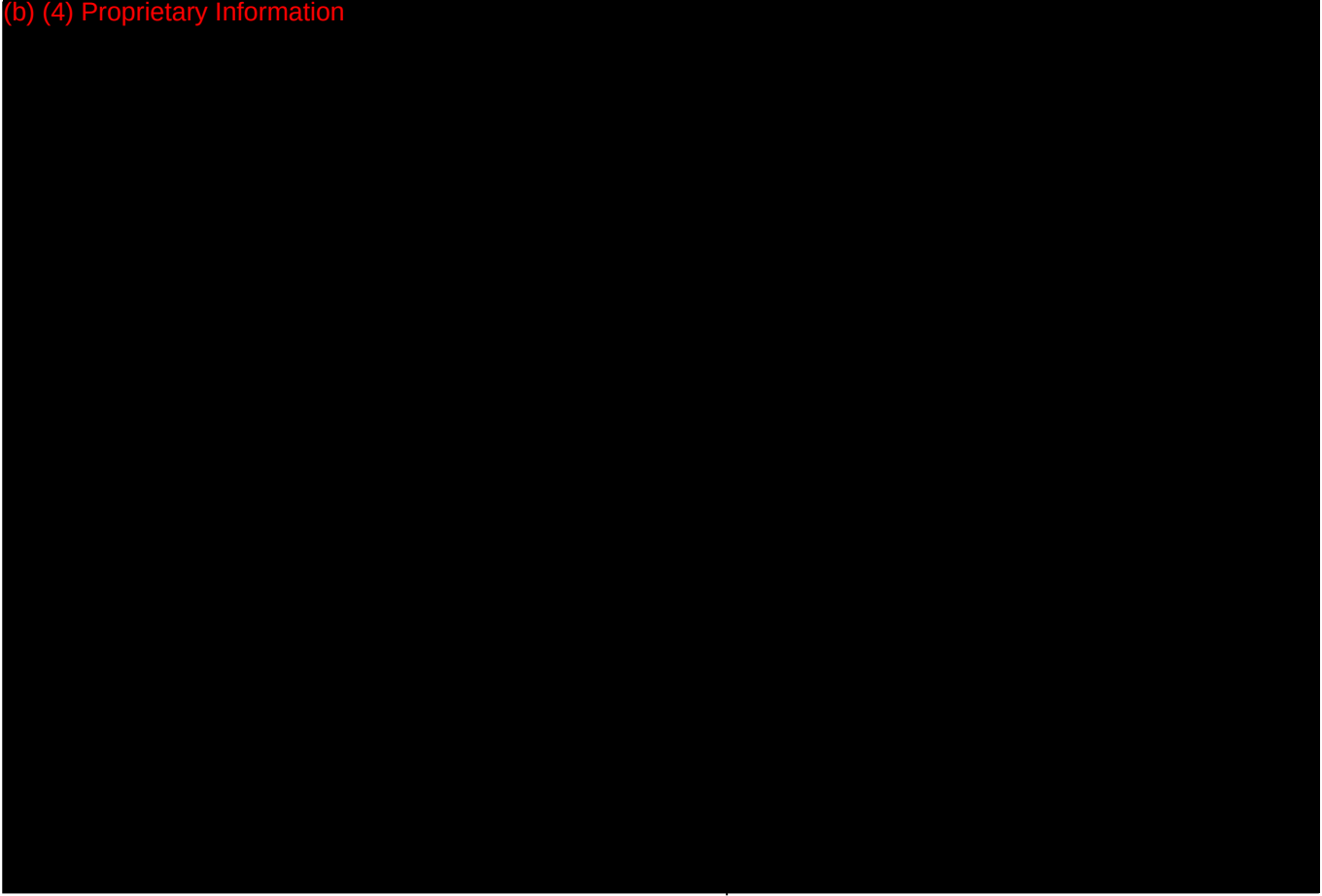
Pulpdent RMGI Fill will be provided non-sterile and is not intended to be sterilized before use. The company has identified the shelf life as 2 years from the date of manufacture.

Biocompatibility

(b) (4) Proprietary Information



(b) (4) Proprietary Information



Software

Pulpdent RMGI Fill contains no software.

Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Pulpdent RMGI Fill is not a mechanical or electrical device. Therefore, mechanical safety, electrical safety, EMC, and thermal safety are not applicable.

Performance Testing – Bench

Engineering performance test results are provided in Section 9, it is summarized as:-

PERFORMANCE TESTING – BENCH

Flexural strength	102 MPa
Compressive strength	280.0 MPa

Flexural modulus	4.3 GPa
Diametral tensile strength	42.0 MPa
Shear bond strength	28 MPa
Polymerization shrinkage	1.7 %
Setting time	
Light Cure	20 s
Self cure (37°C)	2 min 20 s
Self cure (20°C)	3 min 30 s
Radiopacity	Equivalent to 2 mm aluminum

Performance Testing – Animal

Animal test results were not provided for *Pulpdent RMGI Fill*. This type of information is not needed for the assessment of safety and effectiveness of this product.

Performance Testing – Clinical

Human test results were not provided for *Pulpdent RMGI Fill*. This type of information is not needed for the assessment of safety and effectiveness of this product.

Device Comparison

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

Product	Description	Intended Use	Composition
<i>Pulpdent RMGI Fill</i>	Dual-cure, resin-modified glass ionomer in two pastes	Dental restorative/filling material	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

<i>Pulpdent</i> RMGI Low Viscosity K123265	Dual-cure, 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, aluminofluorosilicate ionomer glass, silica, oxidizing agents.
<i>3M Espe</i> Ketac Nano Glass Ionomer Restorative K052235	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Silane-treated glass, zirconia and silica; ionomer glass; Bis-GMA; PEGDMA; HEMA; TEGDMA. Part B: Silane-treated ceramic; co-polymer of acrylic and itaconic acids; HEMA; water.
<i>GC</i> Fuji Filling LC K051427	Light cure, resin-modified glass ionomer in two pastes	Dental restorative	Part A: Aluminofluorosilicate ionomer glass; urethane dimethacrylate; HEMA. Part B: Polyacrylic acid; water; amorphous, fumed silica; urethane dimethacrylate

PHYSICAL AND MECHANICAL PROPERTIES

	<i>PULPDENT</i> RMGI Fill	<i>PULPDENT</i> RMGI Low Viscosity (light-cure)	<i>3M ESPE</i> Ketac Nano	<i>GC</i> Fuji Filling LC
Compressive Strength (MPa)	280	239	236	165
Flexural Strength (MPa)	102	88.0	35	28
Flexural Modulus (GPa)	4.3		5.4	12.3
Diametral Tensile Strength (MPa)	42.0	36	32	15
Shear Bond Strength (MPa) <i>Composite to RMGI Fill</i>	28			
Polymerization Shrinkage	1.7%			

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 main difference between *Pulpdent RMGI Fill* and the predicate is that the revised product uses three setting mechanisms: light cure, self-cure resin chemistry and acid-base glass ionomer reaction. It contains no Bis-GMA, no Bisphenol A and no BPA derivatives. The difference in resin material allows the new product, *Pulpdent RMGI Fill* to improve compressive and flexural strengths. The difference between the predicate devices and *Pulpdent RMGI Fill* is the selection and relative percentages of its components, all of which are found in other legally marketed temporary dental cements. The difference in the selection and percentages of its components has no effect on the safety or efficacy of the device.

The physical properties of *Pulpdent RMGI Fill* appear to be adequate for its intended use.

No new technological characteristics have been introduced in *Pulpdent RMGI Fill* that could affect its safety or effectiveness.

Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

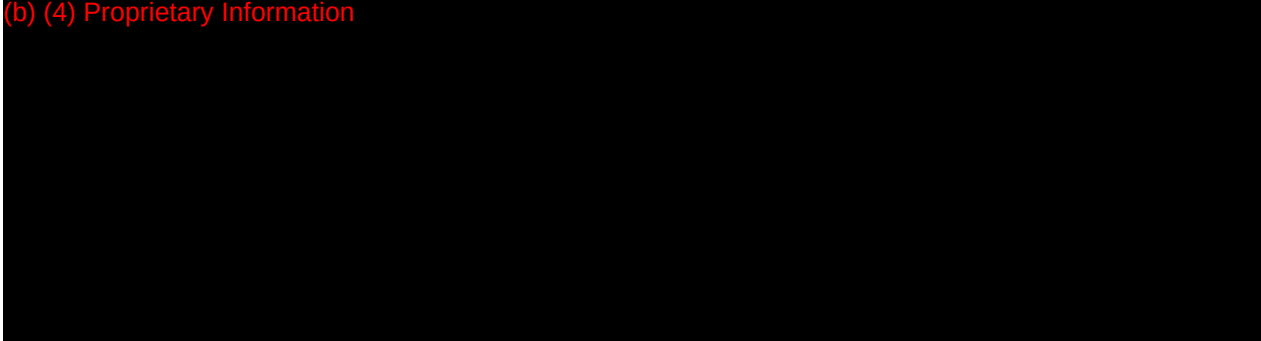
Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:

(b) (4) Proprietary Information



6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Recommendation: SE

Regulation Number: 21 CFR 872.3275
 Regulation Name: Dental cement
 Regulatory Class: Class II
 Product Code: EMA

Digital Signature Concurrence Table	
Reviewer Sign-Off Girish Kumar, PhD Chemical Engineer	Girish Kumar 2013.03.29 08:30:55 -04'00'
Branch Chief Sign-Off M. Susan Runner, DDS, MA Branch Chief Dental Devices	Andrew L. Steen 2013.03.29 09:25:03 -04'00'
Division Sign-Off	Kwame O. Ulmer, S 2013.03.29 13:08:22 -04'00'

Kumar, Girish

From: Ken [ken@pulpdent.com]
Sent: Monday, March 25, 2013 2:30 PM
To: Kumar, Girish
Cc: 'Marjorie Cote'
Subject: 510(k) RMGI Fill K130223
Attachments: 049_510k Summary revised 3.25.13.pdf; 050_EXECUTIVE SUMMARY revised 3.25.13.pdf

Dear Dr. Kumar,

Once again you have proven to be a far better proof reader than I am. Maybe, since I know the words, I don't actually read them.

Attached are new files revising the mistakes you found.

Thank you and best regards,

Ken Berk

Kenneth Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472 USA
Tele: 617-926-6666
Fax: 617-926-6262
ken@pulpdent.com

From: Kumar, Girish [mailto:Girish.Kumar@fda.hhs.gov]
Sent: Monday, March 25, 2013 11:45 AM
To: 'Ken'
Subject: RE: 510(k) RMGI Fill K130223

Dear Mr. Berk,

Thanks for your quick response. I have completed my review of your 510(k) submission, RMGI Fill, K130223. Overall, your responses were found to be acceptable. However, there were a few minor issues in need of further clarification. I was hoping to resolve this request interactively via email, if that is agreeable with you.

Here are the Requests for Additional Information:

1. Is there a typo on page 1 of exhibit 3 (Executive summary)? Under description and intended use paragraph, third and forth sentence mentions the properties of RMGI Low viscosity. Do you think it should be RMGI Fill instead of RMGI Low Viscosity?
2. In 510(k) Summary the device trade name is RMGI Fill, however in the rest of the submission it is "Pulpdent RMGI Fill". Please provide the revised summary so that the device name is consistent in your submission.

Please provide the revised 510(k) summary and revised exhibit 3. FDA requires this information to evaluate substantial equivalence of your device to predicate devices.

Please let me know if you have any further questions or concerns.

Sincerely,

Girish Kumar, PhD

FDA/CDRH/OSEL/DB

FDA/ODE/DAGRID/DEDB

10903 New Hampshire Ave., Bldg. 64,
Room 4036, Silver Spring, MD 20993
301-796-0262, Girish.kumar@fda.hhs.gov

From: Ken [<mailto:ken@pulpdent.com>]
Sent: Tuesday, March 19, 2013 3:27 PM
To: Kumar, Girish
Subject: 510(k) RMGI Fill K130223

Dear Dr. Kumar,

We have not previously submitted an e-Copy. We hope the format of this response is correct.

Attached are three PDF files. 046 is a revised Table of Contents (the changes are the revised PDF file number for the Proposed Labeling and the addition of the PDF file with the Exclusions). 047 is the revised Proposed Labeling as you suggested. 048 is a listing of the Exclusions.

If we have not formatted this properly or if you require additional information, please contact me.

Sincerely,

Ken Berk

Kenneth Berk
Director of Research
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472 USA
Tele: 617-926-6666
Fax: 617-926-6262
ken@pulpdent.com

Dear Mr. Berk,

Good Morning! I hope this finds you well.

I am currently reviewing your 510(k) submission for Pulpdent RMGI Fill (K130223). Please provide the following requested information at your earliest convenience.

1. FDA conducts a comprehensive review of the proposed labeling in accordance with 21 CFR 801.109. Therefore please provide a revised labeling that address the following.
 - o In the proposed labeling (section 5-2 of hard copy), you have provided the indications that do not match the indications of use in section 2 of your submission. Please provide the revised labeling section
2. In your submission sections sterility, software, Electromagnetic compatibility and electrical safety and performance testing are missing. They are mentioned in the checklist and we understand that they are not applicable, however we require them as a part of your submission. Please provide them in a separate sections stating that they are not applicable.

FDA requires this information to evaluate substantial equivalence of your device to predicate devices.

Please email me the information at your earliest convenience and feel free to call me at 301-972-0262 if you have any questions.

Sincerely,

Girish Kumar, PhD

FDA/CDRH/OSEL/DB

FDA/ODE/DAGRID/DEDB

10903 New Hampshire Ave., Bldg. 64,
Room 4036, Silver Spring, MD 20993
301-796-0262, Girish.kumar@fda.hhs.gov

PULPDENT CORPORATION

510 k Premarket Notification
Pulpdent RMGI Fill

510(k) SUBMISSION TABLE OF CONTENTS

Electronic File Name	ELEMENT	HARDCOPY	
		EXHIBIT NUMBER	PAGE
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002	CDRH Premarket Review Submission Cover Sheet		1-2
003	510(k) Cover Letter		1-7
004	Indications for Use Statement	2	2-1
005	510(k) Summary		2-2
006	Truthful and Accuracy Statement		2-7
	Class III Summary and Certification / Not applicable	---	---
	Financial Certification or Disclosure Statement / Not applicable	---	---
	Declarations of Conformity and Summary Reports / Not applicable	---	---
007	Executive Summary	3	3-1
008	Device Specification, Description, Intended Use, Formulas		3-2
009	Substantial Equivalence Comparison	4	4-1
047	Proposed Labeling	5	5-1
	Instructions for Use		5-2
	Material Safety Data Sheet		5-4
	Proposed Advertising		5-6
048	Sterilization / Not applicable	---	---
011	Biocompatibility	6	6-1
	Study Report 1		6-8
	Study Report 2		6-15
	MSDS in e-copy only		
048	Software / Not applicable	---	---
048	Electromagnetic Compatibility and Electrical Safety / Not applicable	---	---
012	Performance Testing – Bench	7	7-1
	Study Report 3		7-6
	Study Report 4		7-20
	Shelf Life Studies: Real Time and Accelerated		7-24
013	Laboratory Testing – Animal (for Biocompatibility)	8	8-1
048	Performance Testing – Clinical / Not applicable	---	---
014	Other: Usability Evaluation	9	9-1
015	Other: Risk Management File	10	10-1

PULPDENT CORPORATION
010_Proposed labeling.docx

510 k Premarket Notification
Pulpdent RMGI Fill

PROPOSED LABELING FOR RMGI FILL

Draft Syringe Label

<u>PULPDENT RMGI Fill</u>		Rx only
Part A – Light sensitive		CE 0459
Resin-modified glass ionomer filling material for use in dental restorations		xx grams
Lot Number: year-month-day		Expiration date: year-month
PULPDENT CORPORATION		
80 Oakland Street, Watertown, Massachusetts 02472 USA		

<u>PULPDENT RMGI Fill</u>		Rx only
Part B		CE 0459
Resin-modified glass ionomer filling material for use in dental restorations		xx grams
Lot Number: year-month-day		Expiration date: year-month
PULPDENT CORPORATION		
80 Oakland Street, Watertown, Massachusetts 02472 USA		

Draft Outer Package

<u>PULPDENT RMGI Fill</u>	Rx only
Resin-modified glass ionomer filling material for use in dental restorations	
Triple Cure • Fluoride Releasing • Hydrophilic • Radiopaque	
Contents: 1 xx gram automix syringe RMGI Fill, xx mixing tips, Instructions for Use, MSDS	
ISO 9917-2 Class 3 Restorative	
 	
 PULPDENT CORPORATION 80 Oakland Street, Watertown, Massachusetts 02472 USA • www.pulpdent.com • Pulpdent@pulpdent.com	

Draft Control Label for Outer Package

REF xxxxxxxx	LOT year-month-day	 20xx-month	Bar code
---------------------	---------------------------	--	----------

PULPDENT CORPORATION
010_Proposed labeling.docx

510 k Premarket Notification
Pulpdent RMGI Fill

PROPOSED LABELING FOR RMGI FILL

INSTRUCTIONS FOR PROPER USE, STORAGE AND HANDLING

Pulpdent RMGI Fill

Rx only

Resin-Modified Glass Ionomer Restorative

Triple Cure • Fluoride Releasing • Hydrophilic • Radiopaque

PRODUCT DESCRIPTION

RMGI Fill is a triple cure formula with three setting mechanisms: light cure, self-cure resin chemistry, and self-cure glass ionomer reaction. The material contains no Bisphenol A, no BisGMA and no BPA derivatives.

INDICATIONS

Recommended as a bioactive filling material for pits, root surface cavities, and Class I, II, III and V, restorations where there is no pulpal involvement.

CONTRAINDICATIONS

Not indicated for direct placement on the exposed pulp. See instructions for use.

PHYSICAL PROPERTIES

Light cure setting time: 20 seconds in increments of 2mm

Self-cure setting time at 37° C: 2 minutes, 20 seconds (intraoral)

Self-cure setting time at 20° C: 3 minutes, 30 seconds (extra-oral)

Percentage filler by weight: 54%

Percentage reactive glass filler by weight: >42

Fluoride release 1 day: 230 ppm

Fluoride release 28 days (cumulative): 940 ppm

Flexural strength: 102 MPa/ 14,790 Psi

Flexural modulus: 4.3 GPa

Compressive strength: 280 MPa / 40,600 Psi

Diametral tensile strength: 42 MPa /6090 Psi

Water sorption (1 week): 1.65%

HOW TO USE THE AUTOMIX SYRINGE

- Remove cap. If necessary bleed the syringe so that base and catalyst are at the orifice of the syringe barrels. Place a mixing tip on the automix syringe.
- To ensure an even mix of base and catalyst, dispense 1-2 mm onto a pad and discard this material.
- Dispense evenly mixed RMGI Fill directly onto the tooth.
- Discard mixing tip. Recap syringe. Do not cross-contaminate base and catalyst.

SLIGHTLY MOIST SURFACES DEFINED

Slightly moist tooth surfaces exhibit neither dryness nor pooling of water. Lightly dry and remove excess water with compressed air or a cotton pellet. Tooth surfaces should be shiny or glossy. Overly wet surfaces will result in decreased bond strength.

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Pulpdent RMGI Fill

PROPOSED LABELING FOR RMGI FILL

INSTRUCTIONS FOR USE

1. Isolate tooth using rubber dam. Avoid water and saliva contamination during the placement of RMGI Fill.
2. Remove carious dentin, and pre-existing restorations and liner materials from the internal aspects of the preparation. Clean, rinse, and lightly dry the preparation leaving the surfaces slightly moist. Do not over dry.
3. In the event of a pulpal exposure, place Pulpdent Paste or Multi-Cal in accordance with the instructions for use. Place a thin layer of RMGI-Fill over the calcium hydroxide paste as a hard base. Light cure or allow to self-cure.
4. Etch entire preparation (enamel, dentin and cementum) with Pulpdent Etch-Rite Etching Gel for 15-20 seconds.
5. Place a mix tip on the RMGI-Fill syringe. To ensure an even mix of base and catalyst, dispense 1-2 mm of material onto a mixing pad and discard this material. Apply a thin layer (2 mm or less) of RMGI-Fill to the prepared surfaces of the cavity and spread the material evenly using a suitable instrument.
6. Closed Sandwich Technique: Do not extend the material over the enamel margins for the closed sandwich technique. Etch remaining enamel cavo surface for 15 seconds, rinse and dry. Apply DenTASTIC UNO or your preferred adhesive bonding agent in accordance with the instructions for use. Place composite and finish restoration.
7. Open Sandwich Technique: extend RMGI-Fill to the enamel cavo surface margin.
8. Add RMGI-Fill Restorative in 2 mm increments, as indicated, curing between each layer.
9. Light Cure for 20 seconds. Intraoral self-cure setting time is 2 minutes 20 seconds.

STORAGE AND HANDLING

- Discard used mixing tips; replace the original sealing cap onto syringe. Use a new tip for each patient.
- Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature (>80°F/27°C, <40°F/5°C), contamination between parts and sources of ignition.
- Shelf life of unopened product: 2 years from date of manufacture.
- Re-cap immediately after use.

Note: Multi-dose syringes should either be encased in a fresh protective barrier for each patient or cleaned and disinfected between patients, as appropriate.

PULPDENT Corporation

80 Oakland Street, Watertown, MA 02472 USA
Tel: (800) 343-4342 / (617) 926-6666 / Fax: (617) 926-6262

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PROPOSED LABELING FOR RMGI FILL

MATERIAL SAFETY DATA SHEET

IDENTITY Pulpdent RMGI Fill
Chemical Description: Resin-modified glass ionomer in two parts with photo-initiator and self-cure chemistry
Product Use: Dental liner, base or luting agent

SECTION I

Pulpdent Corporation Phone Numbers
80 Oakland Street 24 Hour Emergency: 1-800-535-5053
Watertown, MA 02472 USA Customer Service: 1-800-343-4342/1-617-926-6666
Date prepared: January 2, 2013

SECTION II - HAZARDOUS INGREDIENTS

Ingredients	CAS Number	PEL / TLV
Uncured methacrylate resins	-----	Not established
Silica, amorphous	112945-52-5	6 mg/m ³ / 10 mg/m ³
Sodium fluoride	7681-49-4	2.5 mg/m ³ (as F)

DOT HAZARD CLASSIFICATION: None required WHMIS CLASSIFICATION: D-2, Possible irritant
NFPA HMIS RATING: HEALTH: 1 FLAMMABILITY: 0 REACTIVITY: 1

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

Light cure set time	20 seconds
Self-cure set time	3 minutes
Appearance	Two pastes: Part A is yellowish; Part B is off-white
Odor	Slight, characteristic
Specific gravity	Part A: 1.580 ± 0.02 g/mL; Part B: 1.620 ± 0.02 g/mL

SECTION IV - FIRE AND EXPLOSION HAZARD

Flash point: Not established Self-ignition temperature: Not established
Flammable limits: Not established

Hazardous Combustion Products: Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build-up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Extinguishing Media: Carbon dioxide, dry chemical, alcohol foam or water fog. Water spray may be used to keep exposed containers cool.

Special Fire Fighting Procedures: A self-contained breathing apparatus should be worn by fire-fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

SECTION V - REACTIVITY DATA

Stability: Stable Conditions to avoid: Intense light, temperature >80°F/ 27°C, cross-contamination.
Incompatibility: Reducing and oxidizing agents.
Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen
Hazardous Polymerization: None under normal conditions of use.
Conditions to avoid: Strong light, temperature >80°F/ 27°C, cross-contamination.

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SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard in the small quantities present in this product and under normal conditions of use. Material may be irritating to eyes, mucous membranes or skin on contact.

Route of Exposure

Inhalation

Eye Contact

Skin Absorption

Skin Contact

Ingestion

Signs and Symptoms

May be irritating to mucous membranes.

May be irritating.

Not applicable

Primary route of exposure, possibly irritating or sensitizing.

None expected under normal conditions of use. May be irritating to mucous membranes.

Summary of Chronic Hazards: May be sensitizing, especially with prolonged and/or repeated exposure.

Carcinogenicity

Not known to be a carcinogen.

Teratogenicity, Mutagenicity, Reproductive Toxicity: None known

Emergency First Aid Procedures

Inhalation

Move exposed person to fresh air. Seek medical care.

Eye contact

Flush eyes with running water for 15+ minutes. Seek medical attention.

Ingestion

Rinse mouth. Consult physician.

Skin contact

Wash skin with soap and running water. Seek medical attention if irritation persists.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Handling/Storage Precautions: Avoid temperature extremes (>80°F/27°C, <40°F/5°C), strong light, cross-contamination, moisture.

Release or Spill: For small quantities (as in this product): Wear gloves and safety glasses. Pick up with absorbent material (paper or cloth) and collect for suitable disposal.

Waste Disposal Method: Follow all government regulations.

Other Precautions: Wash hands after use.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: Not necessary under normal conditions of use of this product.

Ventilation: No special ventilation required under normal conditions of use of this product.

Protective Gloves: Recommended

Eye Protection: Safety glasses are recommended.

Other Protective Clothing or Equipment: Emergency eye wash fountain should be close by and maintained.

Work / Hygienic Practices: Wash hands after use

The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

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Pulpdent RMGI Fill

PROPOSED LABELING FOR RMGI FILL

Proposed Advertising

PRODUCT 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, *RMGI Fill* 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 Fill is a paste-paste formulation provided in an automix syringe that is used by dental professionals as filling material in dental restorations.

INDICATIONS

Recommended as a bioactive filling material for pits, root surface cavities, and Class I, II, III and V, restorations where there is no pulpal involvement.

CONTRAINDICATIONS

Not indicated for direct placement on the exposed pulp. See instructions for use.

PHYSICAL PROPERTIES

Light cure setting time: 20 seconds in increments of 2mm

Self-cure setting time at 37° C: 2 minutes, 20 seconds (intraoral)

Self-cure setting time at 20° C: 3 minutes, 30 seconds (extra-oral)

Percentage filler by weight: 54%

Percentage reactive glass filler by weight: >42

Fluoride release 1 day: 230 ppm

Fluoride release 28 days (cumulative): 940 ppm

Flexural strength: 102 MPa/ 14,790 Psi

Flexural modulus: 4.3 GPa

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Pulpdent RMGI Fill*

EXCLUSIONS

I. Sterilization

Not applicable. Pulpdent RMGI Fill is not sold sterile or intended to be sterilized by the user.

II. Software

Not applicable. Pulpdent RMGI Fill is a dental material used in restorations and does not contain software.

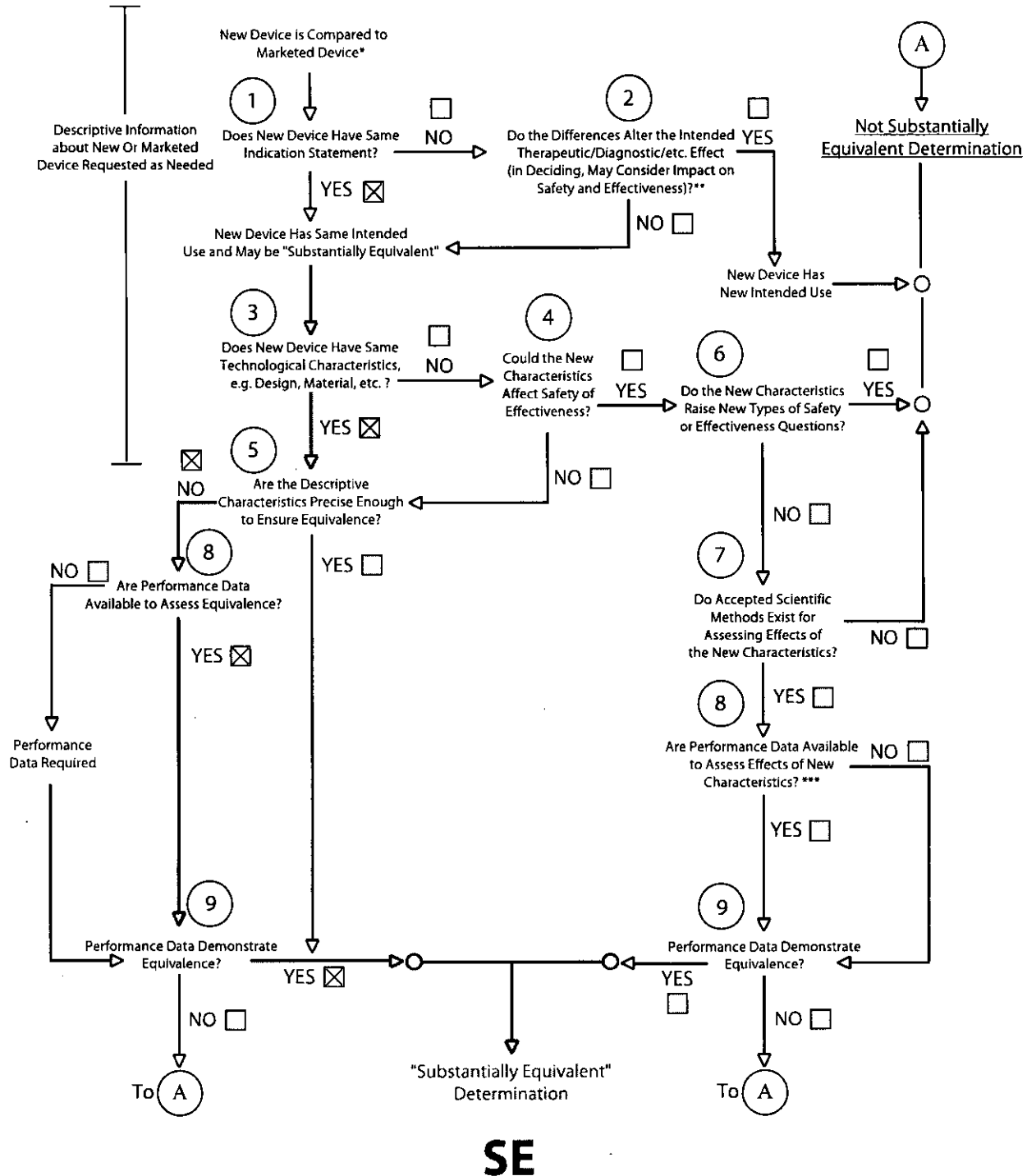
III. Electromagnetic compatibility and electrical safety

Not applicable. Pulpdent RMGI Fill is a dental material used in restorations, which has no electrical component.

IV. Performance Testing – Clinical

Not applicable. Pulpdent RMGI Fill was not the subject of any clinical trial.

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new device to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or literature.