Pulpdent Corporation
% Roger Mastrony
President
MedTek LLC
2516 Kettle Creek Court
Lincolnton, North Carolina 28092

January 17, 2018

Re: K173020
Trade/Device Name: OBA-MCP, Orthodontic Bracket Adhesive with MCP
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin And Tooth Conditioner
Regulatory Class: Class II
Product Code: DYH
Dated: December 12, 2017
Received: December 18, 2017

Dear Roger Mastrony:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173020

Device Name

PULPDENT OBA-MCP - Orthodontic Bracket Adhesive with MCP

Indications for Use *(Describe)*

PULPDENT OBA-MCP is a light-cure orthodontic adhesive composite for the direct and indirect bonding of orthodontic brackets. For dental professional use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY
K173020

DATE OF SUBMISSION: 1/11/18

OWNER: ***Pulpdent Corporation***
80 Oakland Street
Watertown, MA 02472 USA

CONTACT: Roger S. Mastrony
2516 Kettle Creek Court
Lincolnton NC 28092
Tel: 1 203 640 5047 / Email: rogermastrony@gmail.com

TYPE OF SUBMISSION: Traditional 510(k).

DEVICE:
Trade Name: PULPDENT OBA-MCP- *Orthodontic Bracket Adhesive with MCP*
Device Class: II
Review Panel: Dental
Classification Name: Orthodontic Bracket Adhesive
FDA Product Code: DYH; 21 CFR Part 872.3750

PREDICATE DEVICE:

PULPDENT OBA-Orthodontic Bracket Adhesive, Pulpdent Corporation, K911286

REFERENCE DEVICE:

PULPDENT Solo Flowable Composite with MCP, Pulpdent Corporation, K153249

ADDITIONAL PREDICATE DEVICES:

Comparable chemical compositions for the below referenced devices can be found in the Safety Data Sheets for the each product.

3M Unitek Transbond XT Light Cure Adhesive, 3M, K880393 (file 046 in the e-copy)

GC Fuji ORTHO LC Liquid, Fuji, K950556 (file 045 in the e-copy)

DESCRIPTION: ***PULPDENT OBA-MCP*** is a light-cure orthodontic adhesive composite containing modified calcium phosphate that releases fluoride, calcium, and phosphate ions into the oral environment. ***OBA-MCP*** is not formulated with Bisphenol A, BisGMA, or BPA derivatives.

The standards applicable to the subject device, and referenced within the submission, include: *ISO 4049:2009 Dentistry – Polymer based filling, restorative and luting materials*, *ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, *ISO 7405:2008 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*, *ANSI/ADA Standard No. 41 Evaluation of Biocompatibility of Medical Devices Used in Dentistry - ADA41-2005D*.

INDICATIONS FOR USE: ***PULPDENT OBA-MCP*** is a light cure orthodontic adhesive composite for the direct and indirect bonding of orthodontic brackets. For dental professional use only.

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BIOCOMPATIBILITY EVALUATION:

PULPDENT OBA-MCP is substantially equivalent to the predicate device, *Pulpdent OBA*, which has an established history of safe and effective use as a dental material. Pulpdent OBA-MCP is also substantially equiavalent *in chemcial composition* to the reference device, Pulpdent Solo Flowable Composite with MCP, which has been tested with a Cytotoxicity Test (ISO 10993-5 2009) and an Implantation Test (ANSI/ADA Specification 41 and ISO 7405) and found to be biocompatible.

DEVICE COMPARISON WITH PREDICATE AND REFERENCE PRODUCTS

The predicate product has been found to be substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Device under CFR 872.3750, Code DYH.

	Pulpdent OBA – MCP Orthodontic Bracket Adhesive with MCP	***Predicate Product***: PULPDENT OBA, K911286, Orthodontic Bracket Adhesive	***Reference Product***: *optional PULPDENT Solo Flowable Composite with MCP,* K153249
DESCRIPTION	Light cured, adhesive composite, with modified calcium phosphate	Light cured, adhesive composite	Light cured, resin composite with modified calcium phosphate
TECHNOLOGY / MECHANISM OF ACTION	Direct and indirect bonding of orthodontic brackets	Direct and indirect bonding of orthodontic brackets	Dental cavity filler and restorative
INDICATIONS FOR USE	Light cure orthodontic adhesive composite for the direct and indirect bonding of orthodontic brackets	Orthodontic bracket adhesive	Dental restorative, base and liner
COMPOSITION	Aliphatic Dimethacrylates, Diurethane dimethacrylate, Bis (2-(Methacryloyloxy) Ethyl) Phosphate, Barium glass, Strontium glass, MCP (Modified calcium phosphate), Silica, Sodium Fluoride, Camphorquinone (photo-initiators)	1,6 Hexamethylene Dimethacrylate, BisGMA (Bis [4-2 (Hydroxy-3-Methacryloxy Propyl) Phenyl] Propane-2), Dimethylaminoethylmethacrylate, Silanated Barium Glass, Fumed Silica, Sodium Fluoride, Camphorquinone, (photo-initiators)	Aliphatic Dimethacrylates, Diurethane dimethacrylate, Bis (2-(Methacryloyloxy) Ethyl) Phosphate, Barium glass, Strontium glass, MCP (Modified calcium phosphate), Sodium Fluoride, Camphorquinone (photo-initiators), colorants
PHYSICAL PROPERTIES			
Appearance	Stiff, off-white paste	Stiff, off-white paste	Tooth shade paste
Specific gravity	1.9 g/ml	1.820 g/ml	1.810 g/ml
Water Absorption	1.01%		1.73%
Fluoride Release	422 µg/g	Yes	Yes
Phosphate Release	182 µg/g	No	Yes
Calcium Release (pH 4)	96 µg/g	No	Yes

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	Pulpdent OBA – MCP Orthodontic Bracket Adhesive with MCP	***Predicate Product***: PULPDENT OBA, K911286, Orthodontic Bracket Adhesive	***Reference Product***: *optional PULPDENT Solo Flowable Composite with MCP,* K153249
Compressive Strength	353 MPa	---	330 ±47.9
Flexural Strength	112.5 MPa	---	129 ±18.7 MPa
Diametral Tensile Strength	51 MPa	---	46.5 MPa
Light cure set times	20 seconds	20 seconds	20 seconds

Similarities

Pulpdent OBA-MCP and the predicate product, OBA, both share the same technology and mechanism of action, as an orthodontic bracket adhesive. They have essentially the same physical properties and nearly identical chemical formulations.

Differences

Pulpdent OBA-MCP differs from Pulpdent OBA with the addition of MCP (Modified Calcium Phosphate). Additionally, the BisGMA has been removed from the original OBA formulation.

Discussion of the Differences

MCP, or Modified Calcium Phosphate, is a methacrylate moiety, with stabilized calcium and phosphate ions, that is used as a filler in dental materials. In the natural course of the tooth, and its demineralization and remineralization processes in acidic oral environments, there is an ongoing exchange of biologically available calcium and phosphate ions. The addition of calcium and phosphate ions to dental products can be seen in many premarket approved devices. Biocompatability testing performed on products with a similar chemcial composition (including the reference device) have confirmed that a calcium and phospahte addition is biocompatible (see file 012 Biocompatabiltiy Evaluation). It has also been shown that the enamel bond strength of orthodontic materials containing a calcium phosphate moiety exhibits a comparable bond strength to commercially available cements without calcium phosphate. (Zhang, et.al., file _044 in the e-copy)

Conclusion

Taking into account the above similarities and differences, ***Pulpdent*** OBA-MCP Orthodontic Bracket Adhesive with MCP, is substantially equivalent, in design, performance and indications for use, to the predicate product, Pulpdent OBA – Orthodontic Bracket Adhesive.