November 8, 2019

Apex Dental Materials, Inc.
Scott Lamerand
Owner
330 Telser Road
Lake Zurich, Illinois 60047

Re: K190998
Trade/Device Name: BA Pit & Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and fissure sealant and conditioner
Regulatory Class: Class II
Product Code: EBC
Dated: August 8, 2019
Received: August 13, 2019

Dear Scott Lamerand:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190998

Device Name

BA Pit & Fissure Sealant

Indications for Use *(Describe)*

BA Pit & Fissure Sealant is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. 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.

K190998

510(k) Summary
for
BA Pit & Fissure Sealant

Abbreviated 510(k) Submission

1. Applicant

Submitter's Name: Scott Lamerand
Alex Johnson
John Baeten

Date Summary Prepared: Nov. 7, 2019

Address: Apex Dental Materials, Inc
330 Telser Road
Lake Zurich, IL 60047
Registration Number: 3004402215

Contact Person: Scott Lamerand

Phone: 847-719-1133

Email: Scott.Lamerand@apexdentalmaterials.com

Fax: 847-719-1122

2. Device Name

Proprietary Name: BA Pit & Fissure Sealant
Common Name: Sealant, Pit And Fissure, And Conditioner
Review Panel: Dental
Product Code: EBC
Device Class: Class II

3. Predicate Device

Pulpdent (Activa) Pit & Fissure Sealant with MCP (K172169) by Pulpdent Corporation

- Common Name: Sealant, Pit And Fissure, And Conditioner
- Product Code: EBC
- Device Class: Class II

Reference Device

Prevent Seal (K122521) by Itena Clinical

- Common Name: Sealant, Pit And Fissure, And Conditioner
- Product Code: EBC
- Device Class: Class II

4. Device Description

Pit and Fissure sealants are used as a preventive measure to fill defects and prevent decay within crevices, voids or fissures on the surface of teeth. These voids are more challenging to keep free of substances that can lead to caries and eventual breakdown of tooth structure. BA Pit & Fissure Sealant is a material designed to fill these voids with a wear resistant material, ultimately preserving natural tooth structure.

BA Pit & Fissure Sealant is a light activated / photopolymerizable, glass filled, urethane dimethacrylate material that is placed onto an etched enamel surface and light activated for 20 seconds. The result after application is a tooth that has been sealed with a tough, wear resistant material.

This is the only 510(k) for this medical device, no prior 510(k)s have been submitted.

5. Intended Use / Indication for Use

BA Pit & Fissure Sealant is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. For dental professional use only.

6. Technological Characteristics and Substantial Equivalence

	Subject Device	**Predicate Device**	**Reference Device**
Trade Name	BA Pit & Fissure Sealant (K190998)	Pulpdent (Activa) Pit & Fissure Sealant with MCP (K172169)	Prevent Seal (K122521)
Common Name	Pit and Fissure Sealant and Conditioner	Pit and Fissure Sealant and Conditioner	Pit and Fissure Sealant and Conditioner
Device Classification	Class II	Class II	Class II
CFR Section	21 CFR 872.3765	21 CFR 872.3765	21 CFR 872.3765
Product Code	EBC	EBC	EBC
Surface applied to:	Prepared Enamel	Prepared Enamel	Prepared enamel
Number of layers	1	1	1
Method of activation	Light activated only	Light activated only	Light activated only
Duration of activation	20 seconds	20 seconds	20 seconds
Working Time	Unlimited	Unlimited	Unlimited
Indications for Use	BA Pit & Fissure Sealant is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. For dental professional use only.	Pulpdent's Activa Pit and Fissure Sealant with MCP is intended to seal pit and fissure depressions/faults in the enamel, in the biting surfaces of teeth. For dental professional use only.	Prevent Seal is used by dental professionals primarily in young children: -To fill and seal pit and fissure depressions (faults in the enamel) of teeth to prevent cavities; -Covering layer or "initial layer" in the fabrication of esthetically demanding composite restorations; and

	Subject Device	Predicate Device	Reference Device
			-For repairs of composite restorations (in particular filling of voids, leveling out of porosities and minor chips)
Appearance prior to light activation	Milky white paste	Tooth shade paste	White paste
Appearance after light activation	Clear	Clear with tooth shade hue	White / clear
Sterility	Non-sterile	Non-sterile	Non-sterile
Prescription / OTC	Prescription	Prescription	Prescription
Compliance with Standards	ISO 4049:2009 (FDA Recognition Number 4-181) ADA Standard 27 ISO 6874:2015 ISO 14971:2007 ISO 14971:2012 ISO 7405:2009 Guidance for Industry and FDA staff; Dental Composite Resin Devices Premarket Notification [510(k)] Submissions.	ISO 4049:2009 (FDA Recognition Number 4-181) ANSI/ADA Standard 41 ISO 10993-5:2009 ISO 7405:1999 & 2009 Guidance for Industry and FDA staff; Dental Composite Resin Devices Premarket Notification [510(k)] Submissions.	Unknown
Primary Packaging (**)	1.2ml PP syringe	1.2ml PP syringe	1.2ml PP syringe
Co-Packaged Accessories (**)	Applicator tips	Applicator tips	Applicator tips

(**) Primary Packaging (i.e. syringe) and applicator tips are Class I medical devices per EIC product code (syringe, periodontic, endodontic, irrigating) and CFR regulation number 872.4565 and are 510(k) exempt.

Discussion of Similarities between the Subject Device and Predicate Device:

- BA Pit & Fissure Sealant has nearly identical indications for use as its predicate device; the only differences are the medical device and company names.
- BA Pit & Fissure Sealant is classified under product code EBC, with respect to 21 CRF 872.3765 and the common name "Pit and Fissure Sealant and Conditioner", which is identical to that of the predicate device.
- BA Pit & Fissure Sealant has an unlimited working time, and is applied to prepared enamel, which is identical to the predicate device.
- Identical to the predicate device, BA Pit & Fissure Sealant is applied in one layer and is light-activated for 20 seconds by light > 600 mW/cm^2 within 350nm – 490nm.

- BA Pit & Fissure Sealant exhibited a very similar depth of cure to the predicate device, Pulpdent's Pit & Fissure Sealant with MCP.
    - The minor difference between the two devices is not a concern for pit and fissure sealants, since they're used solely on the occlusal surface and in thin layers and does not impact the subject device's suitability for its intended use.
- The composition of BA Pit & Fissure Sealant is identical to existing commercialized medical devices when evaluating components found within both the predicate and reference devices. For example, the predicate device does not contain HEMA, but HEMA is a component within the reference device.
- Identical to the predicate device, BA Pit & Fissure Sealant is packaged within a polypropylene syringe and co-packaged with Class I, 510(k) exempt, applicator tips.
- Identical to the predicate device, BA Pit & Fissure Sealant is commercialized non-sterile, is for prescription use only, and is in compliance with relevant ISO and FDA dental standards and guidances.

  BA Pit & Fissure Sealant shares similar intended use, technical characteristics, packaging configurations, and compositions to the predicate and reference devices. Therefore, BA Pit & Fissure Sealant is substantially equivalent to the predicate device and poses no additional safety or efficacy risks.

Discussion of Differences between the Subject Device and Predicate Device:

- BA Pit & Fissure Sealant has slightly different physical properties (i.e. diametral tensile strength, and pH) compared to the predicate device.
    - These differences do not raise any additional concerns and the subject device remains substantially equivalent to its predicate device.
- Through ion release testing, BA Pit & Fissure Sealant released more calcium, phosphate, and fluoride ions than the predicate device.
    - This difference does not raise concerns as the recorded release profiles are very low (i.e. ppm or ppb) and calcium, phosphate, and fluoride ion levels are known to be safe in this range. Furthermore, the oral environment naturally experiences normal fluctuations in calcium, phosphate, and fluoride ion concentrations through various daily activities (i.e. eating, drinking beverages, brushing teeth, mouthwashes, etc.).
    - In summary, substantial equivalence is supported as the subject device and predicate device released measurable ions in similar concentrations throughout the experiment.

Conclusion:

Taking into consideration the indications for use, application protocol, chemical composition and physical properties of the subject device and reference and predicate devices, the subject device is substantially equivalent to the predicate device. The tables above have provided an overview that details the equivalence. In select instances some comparative data was not available; however, in presenting the available data a comparison of physical properties can be drawn. While select criteria differ, the differences are not clinically relevant and do not impact the suitability of the materials for their intended use.

<u>Applicable Standards</u>

- Dental Composite Resin Devices – Premarket Notification [510(k)] Submissions – Guidance for Industry and FDA Staff, issued on October 26, 2005
- ISO 4049:2009 (FDA Recognition Number 4-181)
- ADA Standard 27
- ISO 6874:2015
- ISO 14971:2007 & ISO 14971:2012
- ISO 7405:2009

7. Non-Clinical Performance Testing and Compliance

BA Pit and Fissure Sealant has undergone extensive benchtop testing to provide evidence that it is substantially equivalent to the predicate device. The following non-clinical tests were conducted to evaluate the functionality, performance, suitability, and substantial equivalence of the subject device to the predicate device:

- Compressive strength
    - BA Pit & Fissure Sealant exhibited a very similar compressive strengths to the predicate device and reference device. Therefore, substantial equivalence of the subject device to the predicate device is supported.
- Diametral tensile strength
    - BA Pit & Fissure Sealant exhibited similar diametral tensile strength compared to the predicate device. Therefore, substantial equivalence of the subject device to the predicate device is supported.
- Elastic modulus
    - The subject device's modulus indicates the material is flexible and will absorb significant forces without reaching permanent deformation. When the material is applied to a tooth surface the level of deformation is limited by the structure of the tooth. With the deformation limited, the BA Pit & Fissure sealant will be able to absorb occlusal forces without experiencing damage. Substantial equivalence of the subject device to the predicate device is supported as the subject device's material properties support efficacious use as a sealant.
- Working time
    - The working time of BA Pit & Fissure Sealant is equivalent to the predicate device, which also has an unlimited working time following testing in ISO 4049. Therefore, substantial equivalence of the subject device to the predicate device is supported.
- Depth of cure
    - BA Pit & Fissure Sealant exhibited a very similar depth of cure of to the predicate device, Pulpdent's Pit & Fissure Sealant with MCP, following ISO 6874 testing. The minor difference between the two devices is not a concern for pit and fissure sealants, since they're used solely on the occlusal surface and in thin layers, and this result does not impact the subject device's safety or efficacy. Therefore, substantial equivalence of the subject device to the predicate device is supported.
- Film thickness
    - BA Pit & Fissure Sealant resulted in a film thickness results nearly equivalent to the reference device, Prevent Seal, following ISO 4049 testing. Therefore, substantial

equivalence of the subject device to commercially available devices in the market is supported.

- Cytotoxicity
    - Both Embrace (predicate device) and BA Pit and Fissure Sealant (subject device) provided the same result in cytotoxicity testing. Therefore, this testing confirms that the subject device is substantially equivalent to the predicate device in terms of cytotoxicity. Combined with the 510(k)'s biocompatibility discussion, and longstanding use of similar dental materials and ingredients for over 30 years, Apex concludes that no further biocompatibility testing or clinical evaluation is needed before release of this product to the market.
- Accelerated shelf-life
    - Accelerated shelf-life testing supports an 18 month shelf-life, as all test points to-date have yielded "passing" results. This test report represents an interim analysis of the accelerated shelf-life testing performed to-date, which currently supports an 18 month shelf-life. Accelerated shelf-life testing will continue through 36 months of accelerated aging to provide a suggested shelf-life for BA Pit and Fissure Sealant. An additional test report will be written to summarize the completed accelerated shelf-life testing. Real-time shelf-life testing will be run in parallel to confirm actual shelf-life parameters for this medical device.
- Ion release
    - Both the subject device and predicate device released measurable calcium, phosphate, and fluoride at each timepoint of the 1 week experiment.
    - Compared to the predicate device, the subject device released more calcium, phosphate, and fluoride over the course of the experiment. However, the oral environment naturally experiences normal fluctuations in ion concentrations, therefore, these minor differences do not raise any concerns. In summary, substantial equivalence is supported as the subject device and predicate device released measurable ions throughout the experiment.

8. Clinical Performance Testing and Compliance

Apex Dental Materials, Inc., concludes that the performed benchtop tests, and longstanding history of these pit and fissure sealants in the dental field, substantiate substantial equivalence of the subject device to the predicate device. As such, clinical performance is not deemed necessary.

9. Conclusion

BA Pit & Fissure Sealant is to be marketed by Apex Dental Materials, Inc, 330 Telser Road, Lake Zurich, IL, 60047, and is substantially equivalent to predicate Pulpdent (Activa) Pit & Fissure Sealant with MCP (K172169). The subject medical device has a nearly identical intended use and technological characteristics to the predicate device, and as such, is substantially equivalent to the predicate device for the described indications. Any differences between the subject medical device and predicate medical device is substantiated by the reference device, scientific dental literature and/or from other medical devices commercially available.