August 10, 2021

Septodont
Greg Montgomery
Business Operations Manager
205 Granite Run Drive, Suite 150
Lancaster, Pennsylvania 17601

Re: K211799
Trade/Device Name: Biodentine XP 500, Biodentine XP 200
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: June 4, 2021
Received: June 10, 2021

Dear Greg Montgomery:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211799

Device Name
Biodentine XP 500, Biodentine XP 200

Indications for Use *(Describe)*
In the crown:
For temporary teeth (children from 2 years of age) and permanent teeth (immature or mature):
- Permanent dentine restoration under composites or Inlay/Onlay
- Temporary dentine-enamel restoration;
- Restoration of deep and/or large coronal carious lesions (sandwich technique);
- Restoration of cervical or radicular lesions.

On the pulp:
For temporary teeth (children from 2 years of age) and permanent teeth (immature or mature):
- Pulp capping (direct and indirect).
- Pulpotomy for diagnosed symptoms of reversible pulpitis and irreversible pulpitis where bleeding is controlled within 5 minutes.

In the root:
For permanent teeth (immature or mature):
- Repair of root perforations;
- Repair of furcation perforations;
- Repair of perforating internal resorptions;
- Repair of external resorption;
- Root-end filling in endodontic surgery (retrograde filling).

For immature permanent teeth
- Apexification;

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.

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5. 510(K) SUMMARY

K211799 **Septodont Biodentine™ XP 500, Biodentine™ XP 200 (per 21CFR 807.92)**

1. SUBMITTER/510(K) HOLDER

Septodont

58, rue du Pont de Créteil
94107 Saint-Maur-des-Fossés, Cedex
France

Phone: 331-49-76-71-16
Establishment Registration No: 9610964
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Contact Phone: +1-(519)-623-4800, x6354
Contact Email: lfillion@septodont.com
Date Prepared: 08/09/2021

2. DEVICE NAME

Device Name:	Biodentine™ XP 500, Biodentine™ XP 200
Device Classification Name:	Resin, Root Canal Filling/Liner, Cavity, Calcium Hydroxide
Regulation Number:	primary : 872.3820
Classification Product Code:	primary: KIF
Device Class:	II

3. PREDICATE DEVICE

Manufacturer:	Septodont
Device Name:	Biodentine™
Device Classification Name:	Resin, Root Canal Filling/Liner, Cavity, Calcium Hydroxide
510(k) Number:	K140132
Regulation Number:	primary: 872.3820, secondary: 872.3275
Classification Product Code:	primary: KIF, secondary: EMA
Device Class:	II

4. DEVICE DESCRIPTION

Biodentine™ XP 500, Biodentine™ XP 200 is a bioactive dentin substitute. The product is prepared from a mixture of a Biodentine™ XP 500, Biodentine™ XP 200 powder and a liquid. The product is presented in all-in-one cartridge containing thepowder phase and the liquid phase, ready to be mixed.

The medical device is presented in two presentations, the Biodentine™ XP 500 for the extraction of 500mg of finished product and the Biodentine™ XP 200 for the extraction of 200mg of finished product. The subject device is to be used with 2 accessories, the Biodentine™ Mixer and the Biodentine™ Gun.

5. INTENDED USE

Bioactive dentin substitute.

6. INDICATIONS FOR USE

In the crown:
For temporary teeth (children from 2 years of age) and permanent teeth (immature or mature):
- Permanent dentine restoration under composites or Inlay/Onlay
- Temporary dentine-enamel restoration;
- Restoration of deep and/or large coronal carious lesions (sandwich technique);
- Restoration of cervical or radicular lesions.

On the pulp:
For temporary teeth (children from 2 years of age) and permanent teeth (immature or mature):
- Pulp capping (direct and indirect).
- Pulpotomy for diagnosed symptoms of reversible pulpitis and irreversible pulpitis where bleeding is controlled within 5 minutes.

In the root:
For permanent teeth (immature or mature):
- Repair of root perforations;
- Repair of furcation perforations;
- Repair of perforating internal resorptions;
- Repair of external resorption;
- Root-end filling in endodontic surgery (retrograde filling).

For immature permanent teeth
- Apexification;

7. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

Septodont demonstrated that, Biodentine™ XP 500, Biodentine™ XP 200 is substantially equivalent in indications and design principles to its predicate device, Septodont's Biodentine™ device, K140132 (cleared on June 27th 2014). The subject device and the predicate device have the same intended used, similar indication for use, same technological characteristics and are made of same materials.

Any differences in their methods of application do not raise any new issues of safety or efficacy for the Biodentine™ XP 500, Biodentine™ XP 200 device.

8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Biodentine™ XP 500, Biodentine™ XP 200 have undergone extensive bench testing to provide evidence that its physical-chemical properties are substantially equivalent to the Biodentine™ predicate device. Both devices are providednon-sterile, have comparable aspect, working time, setting time, compressive strength, sealing ability, pH, porosity, μ hardness and radiopacity.

Biological equivalence has been demonstrated between the subject device, Biodentine™ XP 500, Biodentine™ XP 200 and predicate device, Biodentine™ allowing Septodont to conclude based on Biodentine™ biocompatibilitydata, that Biodentine™ XP 500, Biodentine™ XP 200 is not mutagenic nor a sensitizer or irritant and does not induce any systemic toxicity. It is considered as fully biocompatible and equally bioactive as it is able to induce the mineralization processes.

9. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical data was collected using Biodentine™ XP 500, Biodentine™ XP 200 to support substantial equivalence between the subject and the predicate devices. Clinical equivalence between the two devices has been demonstrated based on the equivalence demonstration in terms of intended use/indications for use, physico- mechanical, chemical, bioactivity and biological properties.
Furthermore, devices are used for the same clinical condition, including similar severity and stage of disease, at the same site in the body (crown, pulp or root of the tooth), in contact with the same tissues (enamel, dentine, pulp), in same population (adult and pediatric populations from 2 years age) and has same relevant critical performance in view of the expected clinical effect for a specific intended purpose. Consequently, the use of the clinical evaluation data obtained using the Biodentine™ is sufficient to demonstrate clinical conformity for the Biodentine™ XP 500, Biodentine™ XP 200.

10. Conclusions Drawn From Non-clinical and Clinical Tests

The subject device, Biodentine™ XP 500, Biodentine™ XP 200 and its predicate device Biodentine™ are designated for equivalent bioactive dentin substitute and have comparable chemical, physical and performance specifications. Both products have equivalent shelf-life. Based on the above information and data provided in this submission, the subject device has been demonstrated to be substantially equivalent to Septodont's cleared device, Biodentine™ (K140132, cleared on 06-27-2014).

Table 5-1. Side-by-Side Comparison of Biodentine™ XP 500, Biodentine™ XP 200 with Predicate Device Biodentine™.

Characteristic	Subject: Biodentine™ XP 500, Biodentine™ XP 200	Predicate: Biodentine™(K140132; cleared on 2014 June 27th)	Comparison (Same, Similar, Different)
Manufacturer	Septodont	Septodont	Same
Classification device code	KIF	KIF /EMA	Same
Classification Name	Resin, Root canal filling	Resin, Root canal filling	Same
Class	Class II	Class II	Same
Intended Use	Bioactive dentine substitute	Bioactive dentine substitute	Same

Indications	In the crown: For temporary teeth (children from 2 years of age) and	In the crown:	Similar
Characteristic	**Subject: Biodentine™ XP 500, Biodentine™ XP 200**	**Predicate: Biodentine™(K140132; cleared on 2014 June 27th)**	**Comparison (Same, Similar, Different)**
	permanent teeth (immature or mature) - Permanent dentine restoration under composites or Inlay/Onlay - Temporary dentine-enamel restoration - Restoration of deep and/or large coronal carious lesions (sandwich technique). - Restoration of cervical or radicular lesions	-Permanent dentine restoration under composites or Inlay/Onlay -Temporary dentine-enamel restoration. -Restoration of deep and/or large coronal carious lesions (sandwich technique). -Restoration of cervical radicular lesions.	
	On the pulp: For temporary teeth (children from 2 years of age) and permanent teeth (immature or mature) - Pulp capping (direct and indirect) - Pulpotomy for diagnosed symptoms of reversible pulpitis and irreversible pulpitis where bleeding is controlled within 5 minutes	-Pulp capping. -Pulpotomy.	Similar

	In the root: For permanent teeth (immature or mature) - Repair of root perforations. - Repair of furcation perforations - Repair of perforating internal resorptions - Repair of external resorption - Root-end filling in endodontic surgery (retrograde filling)	In the root: - Repair of root perforations. - Repair of furcation perforations. - Repair of perforating internal resorptions. - Repair of external resorption - Root-end filling in endodontic surgery (retrograde filling).	Similar
Characteristic	**Subject: Biodentine™ XP 500, Biodentine™ XP 200**	**Predicate: Biodentine™(K140132; cleared on 2014 June 27th)**	**Comparison (Same, Similar, Different)**
	For immature permanent teeth: - Apexification	- Apexification.	
User population	Biodentine™ XP 500, Biodentine™ XP 200 is intendedto be applied on temporary teeth (from 2 years old), on permanent teeth (mature or immature) or on non-vital immature permanent teeth depending on indication.	Information not provided in Biodentine™ label submitted in K140132.	Similar; User population information in label is now required for all Septodont's product
Prescription/ over-the-counter use	Prescription	Prescription	Same
Single-use /multiple use	Single use	Single use	Same
Galenic Forms	Powder/Liquid	Powder/Liquid	Same
Ingredients	**Powder**: tricalcium silicate, zirconium oxide, calcium oxide, calcium carbonate, iron-oxide based pigments **Liquid**: calcium chloride, polycarboxylate, purified water	**Powder**: tricalcium silicate, zirconium oxide, calcium oxide, calcium carbonate, iron-oxide based pigments **Liquid**: calcium chloride, polycarboxylate, purified water	Same

Ingredients quantity	XP500: Powder: 700mg Liquid: 190µL XP200 : Powder: 450mg Liquid: 122µL	Capsule of powder : 700mg Single-dose container of liquid : 250µL The dental healthcare professional put 5 or 6 drops into the capsule powder i.e 173µL to 208µL	Similar; ratio powder/liquid (w/w) is equivalent for subject device (XP500 (3.04) and XP200 (2.91)) compared to predicate device (between 2.79 and 3.34).
Liquid formulation	In XP200 and XP500 formulation: For 100 g quantity: Plasticizer: 0.5 g Purified water: 70.10 g	For 100 g quantity: Plasticizer: 2.0 g Purified water: 68.60 g	Similar; Biodentine™ XP liquid formulation is similar to Biodentine™liquid formulation.
Characteristic	**Subject: Biodentine™ XP 500, Biodentine™ XP 200**	**Predicate: Biodentine™(K140132; cleared on 2014 June 27th)**	**Comparison (Same, Similar, Different)**

			The ingredients are the same but the quantity for the plasticizer agent and the purified water are different from the predicate. Performance equivalence has been demonstrated on subject and predicate finished products demonstrating that the difference in plasticizer quantity in the liquid formulation does not impact product specifications when compared subject device (XP500 and XP200) to predicate device.
Containers	Powder and liquid are packaged in the all-in-one Biodentine™ XP 500, Biodentine™ XP 200 single-dose cartridge	Powder in capsule Liquid in single-dose container	Different; however, stability results obtained for subject device provide equivalent shelf life than the
Characteristic	**Subject: Biodentine™ XP 500, Biodentine™ XP 200**	**Predicate: Biodentine™(K140132; cleared on 2014 June 27th)**	**Comparison (Same, Similar, Different)**

			predicate device. Human factor study has provided evidence of safety and effectiveness for the subject device.
Mixing and Dispensing	Mixing: using the Biodentine™ Mixer Dispensing: using the Biodentine™ Gun dispenser by the dental healthcare specialist	Mixing: using a mixer Dispensing: Manually by the dental healthcare specialist	Same for mixing step. Different for the dispensing step, however human factor study has provided evidence of safety and effectiveness for the subject device.
Working Time	≥ 1min	≥ 1min	Same
Setting Time (at 37ºC)	9 to 25 min (average time of 12.5 minutes)	9 to 25 min (average time of 12.5 minutes)	Same
Compressive strength	≥ 150 MPA at 24h	≥ 150 MPA at 24h	Same