September 16, 2021

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

Re: K212283
Trade/Device Name: BioRoot Flow 0.5g, BioRoot Flow 2g
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: July 19, 2021
Received: July 21, 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)*
K212283

Device Name
BioRoot Flow 0.5g, BioRoot Flow 2g

Indications for Use *(Describe)*

- Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp.
- Permanent root canal filling in combination with gutta-percha points following a retreatment procedure.

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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5. 510(K) Summary K212283

Septodont
BioRoot™ Flow 0.5g, BioRoot™ Flow 2g
(per 21 CFR 807.93)

1. SUBMITTER/510(K) HOLDER

Septodont
58, rue du Pont De Créteil
Saint-Maur des Fossés Cedex
Phone: 331-49-76-71-16
Establishment Registration No: 9610964

Contact: Leslie Fillion, Regulatory Affairs Manager
Contact Phone: 1-519-623-4800 Ext. 6354
Contact Email: lfillion@septodont.com
Date Prepared: July 13, 2021

2. DEVICE NAME

Device Name:	BioRoot™ Flow 0.5g, BioRoot™ Flow 2g
Device Classification Name:	Resin, Root Canal Filling/Dental Cement
Regulation Number:	Primary: 872.3820, Secondary: 872.3250
Classification Product Code:	KIF
Device Class:	Class II

3. PREDICATE DEVICE

Primary Predicate

Manufacturer:	Septodont
Device Name:	BioRoot™ RCS
Device Classification Name:	Resin, Root Canal Filling/Dental Cement
510(k) Number:	K130601
Regulation Number:	Primary: 872.3820, Secondary: 872.3250
Classification Product Code:	KIF
Device Class:	Class II

Secondary Predicate

Manufacturer:	Innovative BioCeramix Inc
Device Name:	iRoot SP
Device Classification Name:	Resin, Root Canal Filling/Dental Cement
510(k) Number:	K080917
Regulation Number:	Primary: 872.3820, Secondary: 872.3250
Classification Product Code:	KIF
Device Class:	Class II

4. DEVICE DESCRIPTION

BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is hydrophilic mineral root canal sealer presented as a ready-to-use paste in a syringe. BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is based on a tricalcium silicate reaction with *in situ* water to seal the root canal. The sealer ensures a good adaptation to the root canal, tight interface with gutta-percha point and an adequate radiopacity.

It is an implantable medical device intended to be used in dentistry. It is part of endodontic cements used as permanent root canal sealer. BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is used in combination with gutta-percha points to fill the root canal.

5. INDICATION FOR USE/INTENDED USE

The intended use for BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is:

- Permanent root canal sealer

The indications for BioRoot™ Flow 0.5g, BioRoot™ Flow 2g are:

- Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp.
- Permanent root canal filling in combination with gutta-percha points following a retreatment procedure.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICES

Septodont demonstrated that BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is substantially equivalent to the predicate devices, BioRoot™ RCS (K130601, cleared 17-Oct-2013) and iRoot SP (K080917, cleared 09-Apr-2008), in regards to the indications and basic design principles. The indications, technological characteristics and overall design of the subject device are substantially equivalent to those of the predicate devices, with any differences limited to minor differences in design and performance that do not raise any new questions of safety or effectiveness.

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

BioRoot™ Flow 0.5g, BioRoot™ Flow 2g has undergone extensive bench testing to provide evidence that its physical-chemical properties are substantially equivalent to the predicate devices, BioRoot™ RCS and iRoot SP. All three (3) devices are provided non-sterile, have comparable setting time, sealing and adhesion.

Biocompatibility test results determined that considering all existing data resulting from the chemical characterization and associated toxicological risk assessment,

and from biological data, the biocompatibility profile of BioRoot™ Flow 0.5g, BioRoot™ Flow 2g can be considered acceptable when used as intended.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Clinical equivalence between BioRoot™ Flow 0.5g, BioRoot™ Flow 2g and the primary predicate, BioRoot™ RCS, was demonstrated based on equivalence in terms of the intended use, indications for use, technical, mechanical and biological properties. Furthermore, BioRoot™ Flow 0.5g, BioRoot™ Flow 2g and BioRoot™ RCS are used for the same clinical indication, at the same site in the body (root canal of the tooth), are in contact with the same tissues (root canal dentine), in the same population (mature and permanent teeth) and have the same clinical performance in regards to the expected clinical effect for a specific intended purpose. Clinical evaluation data obtained using the equivalent device, BioRoot™ RCS, was used to support clinical evidence of BioRoot™ Flow 0.5g, BioRoot™ Flow 2g and can be extended to BioRoot™ Flow 0.5g, BioRoot™ Flow 2g in terms of clinical performance and clinical safety.

9. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The subject device, BioRoot™ Flow 0.5g, BioRoot™ Flow 2g, and its' predicate devices, BioRoot™ RCS and iRoot SP, have demonstrated to be substantially equivalent and have comparable chemical, physical and performance specifications. Based on the above information and the data provided, the subject device has demonstrated to be substantially equivalent to both the primary predicate device, BioRoot™ RCS (K130601, cleared 17-Oct-2013), and the secondary predicate device, iRoot SP (K080917, cleared 09-Apr-2008).

Side-by-Side Comparison of BioRoot™ Flow 0.5g, BioRoot™ Flow 2g with BioRoot™RCS and iRoot SP

Characteristic	BioRoot™ Flow 0.5g, BioRoot™ Flow 2g (Subject Device)	BioRoot™ RCS (Primary Predicate Device - K130601)	iRoot SP (Secondary Predicate Device – K080917)	Similarities and Differences between Subject Device and Predicate Devices
Manufacturer	Septodont	Septodont	Innovative BioCeramix Inc.	N/A
Classification device code	KIF	KIF	KIF	Same; Substantially Equivalent
Classification Name	Resin, Root canal filling	Resin, Root canal filling	Resin, Root canal filling	Same; Substantially Equivalent
Class	Class II	Class II	Class II	Same; Substantially Equivalent
Intended Use	Permanent root canal sealer	Permanent root canal sealer	Permanent root canal sealer	Same, Substantially Equivalent

Characteristic	BioRoot™ Flow 0.5g, BioRoot™ Flow 2g (Subject Device)	BioRoot™ RCS (Primary Predicate Device - K130601)	iRoot SP (Secondary Predicate Device – K080917)	Similarities and Differences between Subject Device and Predicate Devices
Indications	Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp. Permanent root canal filling in combination with gutta-percha points following a retreatment procedure.	Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp. Permanent root canal filling in combination with gutta-percha points following a retreatment procedure. BioRoot™ RCS is suitable for use in single cone technique or cold lateral condensation.	Permanent obturation of the root canal following vital pulp-extirpation. Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.	iRoot SP - Similar, indications statement does not mention gutta-percha points BioRoot™ RCS – Similar, does not include the statement regarding being suitable for use in single cone technique or cold lateral condensation (due to the change in design, obturation is no longer limited to specific techniques).
Intended Users	Dental healthcare professional.	Dental healthcare professional.	Dental healthcare professional.	Same, Substantially Equivalent
Intended Patient Population	Permanent and mature teeth	Permanent and mature teeth	Permanent and mature teeth	Same, Substantially Equivalent
Prescription/ over-the-counter use	Prescription	Prescription	Prescription	Same, Substantially Equivalent
Single-use/ multiple use	Multi-Use Device (only the tips are considered single use)	Single Use Device (The bottle of powder is multi-use, whereas the single dose containers are single use)	Multi-Use	iRoot SP - Same; Substantially Equivalent
Galenic Forms (Delivery System)	Paste (paste syringe)	Powder/Liquid (powder liquid mixing)	Paste (paste syringe)	iRoot SP - Same; Substantially Equivalent

Characteristic	BioRoot™ Flow 0.5g, BioRoot™ Flow 2g (Subject Device)	BioRoot™ RCS (Primary Predicate Device - K130601)	iRoot SP (Secondary Predicate Device – K080917)	Similarities and Differences between Subject Device and Predicate Devices
Ingredients and quantities	Paste (per 100g): • Tricalcium silicate (36.07g) • Zirconium oxide (30.00g) • Calcium carbonate (3.50g) • Propylene glycol (27.93g) • Polyvidone K90 (1.00g) • Sepineo P600 (1.00g) • Aerosil R1812S (0.50g)	Powder (per 100g): • Tricalcium silicate – Micronized C3S (30.00g) • Tricalcium silicate (30.00g) • Zirconium oxide (35.00g) • Polyvidone K90 (5.00g) Liquid (per 100g): • Dihydrated Calcium Chloride (29.40g) • Neomere Tech (2.00g) • Purified water (68.60g)	Paste: • Tricalcium silicate • Dicalcium silicate • Calcium Phosphate • Zirconium oxide • Calcium hydroxide • Solvent • Gelifying Agent • Stabilizer Quantities are unknown as this is proprietary information.	The ingredients contained in BioRoot™ Flow 0.5g, BioRoot™ Flow 2g and iRoot SP are similar and determined to be substantially equivalent. BioRoot™ Flow 0.5g, BioRoot™ Flow 2g performance testing has demonstrated substantial equivalence to BioRoot™ RCS. BioRoot™ Flow 0.5g, BioRoot™ Flow 2g has similar ingredients to BioRoot™ RCS with a few additional ingredients to allow for the paste. The quantities also differ between the two devices however once reconstituted the cements have the same amount of Tricalcium silicate and Zirconium oxide (approx. 66%) indicating an equivalent composition. Performance reports have demonstrated substantial equivalence (refer to Section 18).
Containers	Premixed paste is contained in a syringe	Powder is packaged in a capsule; liquid is packaged in a single dose container	Premixed paste is contained in a syringe	iRoot SP - Same; Substantially Equivalent BioRoot™ RCS - Different; container closure system is different due to different delivery system
Operations (Mixing and Dispensing)	No mixing required, product is a ready-to-use paste	Mixing: liquid added to powder and mixed by hand by the dentist.	No mixing required, product is a ready-to-use paste	iRoot SP - Same; Substantially Equivalent

Characteristic	BioRoot™ Flow 0.5g, BioRoot™ Flow 2g (Subject Device)	BioRoot™ RCS (Primary Predicate Device - K130601)	iRoot SP (Secondary Predicate Device – K080917)	Similarities and Differences between Subject Device and Predicate Devices
				BioRoot™ RCS - Different; mixing is required as it requires reconstitution of the powder and liquid.
Consistency	Paste	Not Performed (not a paste)	Paste	iRoot SP - Same; Substantially Equivalent
Setting Time	1h to 6h	55min to 300min	4h	Performance testing have demonstrated that BioRoot™ Flow 0.5g, BioRoot™ Flow 2g is substantially equivalent to BioRoot™ RCS and iRoot SP sealer regarding setting time.