Angelus Industria de Produtos Odontologicos S/A
Juliana Norder
International Regulatory Affairs Analyst
Rua Waldir Landgraf, 101
Londrina, 86.031-218 Br

August 31, 2018

Re: K180185
Trade/Device Name: BIO-C Repair
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: January 12, 2018
Received: January 23, 2018

Dear Juliana Norder:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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)*

Device Name
BIO-C REPAIR

Indications for Use *(Describe)*

1. Furcation or root perforation treatment via canal;
2. Furcation or root perforation treatment via surgical;
3. Internal reabsorption treatment via canal or surgical;
4. External reabsorption treatment;
5. Retrofilling in parendodontic surgery;
6. Direct and indirect pulp capping;
7. Apexification;
8. Apexogenesis and Pulpotomy.

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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510(k) Summary

Angelus Indústria de Produtos Odontológicos S/A

BIO-C REPAIR

August 31, 2018

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Angelus Indústria de Produtos Odontológicos S/A Rua Waldir Landgraf, 101 Londrina, PR 86031-218 Brazil Telephone: +55 (43) 2101-3200 Fax: +55 (43) 2101-3201
Official Contact:	Juliana Norder International Regulatory Affairs Analyst juliana.norder@angelus.ind.br

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BIO-C REPAIR
Common Name:	Root Canal Filling Resin
Classification Regulation:	21 CFR 872-3820, Class II
Product Code:	KIF
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch
Primary Predicate Device:	K082943 iRoot BP (Innovative BioCeramix Inc.)
Secondary Reference Device:	K172701 BIO-C SEALER (Angelus Indústria de Produtos odontológicos S.A)

DEVICE DESCRIPTION

BIO-C REPAIR is a ready-to-use bioceramic MTA-based paste developed for permanent root canal repair and surgical applications. The product is a single paste provided in a syringe with disposable tips to be applied to the affected area of the root canal system. BIO-C REPAIR is an insoluble and radiopaque material which requires the presence of water to set and harden.

PRODUCT PRESENTATION

Reference	Product Description	Package Contents
3863	BIO-C REPAIR	• 4 preloaded syringes with 0.5g each • 20 disposable intracanal tips

INTENDED USE

Reparative cement for endodontic complications.

INDICATIONS FOR USE

1. Furcation or root perforation treatment via canal;
2. Furcation or root perforation treatment via surgical;
3. Internal reabsorption treatment via canal or surgical;
4. External reabsorption treatment;
5. Retrofilling in parendodontic surgery;
6. Direct and indirect pulp capping;
7. Apexification;
8. Apexogenesis and Pulpotomy.

EQUIVALENCE TO MARKETED DEVICE

Angelus Indústria de Produtos Odontológicos S/A demonstrated that, for the purposes of FDA's regulation of medical devices, BIO-C REPAIR is substantially equivalent in indications and design principles to the following predicate device:

INNOVATIVE BIOCERAMIX INC., **iRoot BP** cleared under **K082943**

The subject device and the predicate device have the same intended use and same technological characteristics and are made of similar materials. They encompass the same range of physical and chemical properties. The subject and predicate devices are packaged in similar materials and use similar methods of application.

Any differences in specific components do not raise new issues of safety or efficacy. Even though BIO-C REPAIR's main chemical composition is based on **iRoot BP**, as mentioned above, the additional chemical components in BIO-C REPAIR's composition and the delivery system were found in the following predicate device:

ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A, **BIO-C SEALER** cleared under **K172701.**

COMPARISON TO THE CLEARED DEVICES

BIO-C REPAIR and iRoot BP are designated for the equivalent dental applications, have comparable chemical and physical properties and performance specifications. The secondary reference device, BIO-C SEALER, contains specific chemical components that are found in BIO-C REPAIR; providing evidence that these chemical components are safe and effective for medical device use and therefore does not affect the substantial equivalence. Furthermore, BIO-C REPAIR and BIO-C SEALER (K172701) have identical delivery systems (syringe and disposable intracanal tips).

The similarities and differences of BIO-C REPAIR and the predicates are discussed below:

- ✓ BIO-C REPAIR, iRoot BP and BIO-C SEALER are mainly composed of tricalcium silicate and dicalcium silicate. These ingredients are responsible for physical and biological properties of both products.
- ✓ Zirconium oxide is present in BIO-C REPAIR, iRoot BP and BIO-C SEALER compositions. This ingredient is responsible for the radiopacity of the products.
- ✓ BIO-C REPAIR and BIO-C SEALER uses calcium oxide as Ca^{2+} an OH^- sources while iRoot BP relies only on calcium silicates to provide calcium and hydroxyl ions.
- ✓ BIO-C REPAIR and BIO-C SEALER share the same dispersing agent, while iRoot BP does not discloses its carrier.
- ✓ iRoot BP also contains calcium phosphate monobasic and tantalum pentoxide, unlike BIO-C REPAIR and BIO-C SEALER.
- ✓ BIO-C REPAIR, iRoot BP and BIO-C SEALER share the same Delivery System (syringe and disposable intracanal tips).

Therefore, it is concluded that BIO-C REPAIR is substantially equivalent to the predicate devices.

The table below summarizes the main similarities of BIO-C REPAIR and the predicate devices:

Element	**Proposed Device**	**Predicate Device (K082943)**	**Reference Device (K172701)**
Trade Name	BIO-C REPAIR	iRoot BP	BIO-C SEALER
Manufacturer	ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A	INNOVATIVE BIOCERAMIX INC.	ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A
Device Description	BIO-C REPAIR is a ready-to-use bioceramic reparative cement.	iRoot BP Injectable Root Canal Repair Filling Material is a convenient ready-to-use white hydraulic premixed injectable paste developed for permanent root canal repair and filling applications.	BIO-C SEALER is a ready-to-use injectable endodontic bioceramic Sealer, suitable for obturation of root canals.
Common Name	Root Canal Filling Resin	Root Canal Filling Resin	Root Canal Filling Resin
Class	Class II	Class II	Class II
Product Code	KIF	KIF	KIF
Composition	Calcium silicates Calcium oxide Zirconium oxide Silicon oxide Iron oxide Dispersing agent	Tricalcium silicate Dicalcium silicate Calcium phosphate monobasic Zirconium oxide Tantalum Pentoxide Filler agents	Calcium silicates Calcium oxide Zirconium oxide Silicon oxide Iron oxide Dispersing agent
Principle of operation	BIO-C REPAIR is an insoluble and radiopaque root repair material which requires the presence of water to set and harden. Calcium hydroxide is produced due to the hydration reaction of the calcium silicates and calcium oxide increasing the pH of the medium.	iRoot BP is a ready-to-use white hydraulic premixed injectable paste developed for permanent root canal repair and filling applications. iRoot BP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot BP does not shrink during setting and is packaged in a preloaded syringe and is supplied with disposable tips.	BIO-C SEALER is an insoluble and radiopaque root canal sealer which requires the presence of water to set and harden. Calcium hydroxide is produced due to the hydration reaction of the calcium silicates and calcium oxide increasing the pH of the medium.
Indications for use	1. Furcation or root perforation treatment via canal; 2. Furcation or root perforation treatment via surgical; 3. Internal reabsorption treatment via canal or surgical; 4. External reabsorption treatment;	Repair of Root Perforation Repair of Root Resorption Root End Filling Apexification Pulp Capping	Sealing the root canal of permanent teeth; Internal reabsorption treatment.

	5. Retrofilling in parendodontic surgery; 6. Direct and indirect pulp capping; 7. Apexification; 8. Apexogenesis and Pulpotomy.		
Delivery form	Single paste	Single paste	Single paste
Design	Syringe Disposable Intra Canal tips	Syringe Disposable Intra Canal tips	Syringe Disposable Intra Canal tips
Nature of contact	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)	Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (>30 days)
Sterile	Non-sterile	Non-sterile	Non-sterile
pH	12.5	> 12	12.5
Setting time	90 - 120 minutes	~ 2 hours	120-240 minutes
Radiopacity	≥ 7 mm Al	~ 7 mm Al	≥ 7 mm Al
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Contraindications	Do not use it in patients that report sensitivity to the components of the formula.	Do not use in patients with a known allergy to any of the product's ingredients.	Do not use it in patients that report sensitivity to the components of the formula.
Shelf Life	2 years	2 years	2 years
Environment of use	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital
Intended environment	Dental offices	Dental offices	Dental offices
Intended users	Dental practitioners	Dental practitioners	Dental practitioners
Intended patient population	Patients who require endodontic treatment.	Patients who require endodontic treatment.	Patients who require endodontic treatment.
Storage	Keep the product in a dry and ventilated place between 15 and 30°C and with relative humidity below 60%. Do not store it in a refrigerator. Do not store the product near ammonia, ammonium nitrate and products containing chlorine. Avoid using disinfectant solutions that contain any of these ingredients.	- Keep tightly closed in its sealed package and store it at room temperature in a dry area, to avoid moisture contact, which could induce the setting process. - Be certain to tightly secure the lid of the jar after each use. - Use the syringe cap to keep the syringe tightly closed when not using the material. - Do not use excessive force to apply the material into the root canal, as this may cause acute pain to the patient.	Keep the product in a dry and ventilated place between 15 and 30°C and with relative humidity below 60%. Do not store it in a refrigerator. Do not store the product near ammonia, ammonium nitrate and products containing chlorine. Avoid using disinfectant solutions that contain any of these ingredients.

PERFORMANCE DATA OR NON-CLINICAL EVIDENCE

BIO-C REPAIR has undergone extensive bench testing to provide evidence that its physical-chemical properties are substantially equivalent to iRoot BP. The following bench tests were performed according to ISO 6876:2012 *Dental root canal sealing materials*: setting time, solubility and radiopacity.

Both devices are provided non-sterile and have comparable setting time, pH and radiopacity. Although we did not find the solubility of the predicate, our product when subjected to solubility tests presented values in accordance with the established by the international standard.

CONCLUSION

BIO-C REPAIR and its predicate device are designated for equivalent dental applications and have comparable chemical and physical properties and performance specifications. Furthermore, BIO-C REPAIR and its predicate device have equivalent shelf life, packaging containers and delivery systems.

Based on the information provided in the premarket notification, we can conclude that the subject device is substantially equivalent to the predicate device.