February 11, 2021

Angelus Industria de Produtos Odontologicos S/A
Juliana Trostdorf
International Regulatory Affairs Coordinator
Rua Waldir Landgraf, 101
Londrina, PR 86.031-218
BRAZIL

Re: K201222
Trade/Device Name: Bio-C Repair Ion+
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: November 19, 2020
Received: November 19, 2020

Dear Juliana Trostdorf:

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 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)*
K201222

Device Name
BIO-C REPAIR ION+

Indications for Use *(Describe)*

- Furcation or root perforation treatment via canal;
- Furcation or root perforation treatment via surgical;
- Internal reabsorption treatment via canal or surgical;
- External reabsorption treatment;
- Retrofilling in parendodontic surgery;
- Direct and indirect pulp capping;
- Apexification;
- 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 ION$^+$

K201222

ADMINISTRATIVE INFORMATION

Date prepared:	April 30th, 2020.
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 Trostdorf Regulatory Affairs Coordinator juliana.norder@angelus.ind.br

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	BIO-C REPAIR ION$^+$
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:	K180185 BIO-C REPAIR (Angelus Indústria de Produtos Odontológicos S/A)
Reference Device:	K190537 BIO-C SEALER ION$^+$ (Angelus Indústria de Produtos Odontológicos S/A)

DEVICE DESCRIPTION

BIO-C REPAIR ION$^+$ is a bioceramic reparative material ready-to-use suitable for furcation or root perforation treatment via canal, furcation or root perforation treatment via surgical, internal reabsorption treatment via canal or surgical, external reabsorption treatment, retrofilling in parendodontic surgery, direct and indirect pulp capping, apexification, apexogenesis and pulpotomy.

The product is a single paste provided in a syringe with blunt tips to be applied into the root canal system. BIO-C REPAIR ION$^+$ is an insoluble and alkaline material, which requires the presence of water to set and harden. The product presents suitable radiopacity, demonstrating adequate physical properties inherent to root repair materials.

PRODUCT PRESENTATION

Reference	Product Description	Package Contents
3912	BIO-C REPAIR ION$^+$	1 syringe with 0.5 g
3913	BIO-C REPAIR ION$^+$	2 syringes with 0.5 g
3914	BIO-C REPAIR ION$^+$	4 syringes with 0.5 g

INTENDED USE

Reparative material 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.

COMPARISON OF TECHNOLOGY

BIO-C REPAIR ION$^+$ and BIO-C REPAIR are indicated for equivalent dental applications, have comparable chemical/physical properties and performance specifications and equivalent delivery systems (ready-to-use syringe). The reference device, BIO-C SEALER ION$^+$, contains the same chemical components that is found in BIO-C REPAIR ION$^+$;

The similarities and differences of BIO-C REPAIR ION$^+$ and the predicates are discussed below:

- ✓ BIO-C REPAIR ION$^+$, BIO-C REPAIR and BIO-C SEALER ION$^+$ are mainly composed of calcium silicates. BIO-C REPAIR ION$^+$ and BIO-C SEALER ION$^+$ are composed of calcium and magnesium silicate, and BIO-C REPAIR is composed of calcium silicates. Despite the difference between the silicates in the formulations, biocompatibility tests were conducted with BIO-C REPAIR and BIO-C SEALER ION$^+$ and the results demonstrated that the devices are biocompatible.
- ✓ BIO-C REPAIR ION$^+$ and BIO-C SEALER ION$^+$ uses calcium sulfate as setting agent, whereas BIO-C REPAIR sets in the presence of moisture due to the hydration of the calcium silicates.
- ✓ As BIO-C REPAIR ION$^+$, BIO-C REPAIR and BIO-C SEALER ION$^+$ are pre-mixed ready-to-use pastes, a biocompatible hydrophilic polymer is used in order to give an adequate viscosity and flow to the products. In this case, this polymer is included as a chemical component in all three materials and is also present in several cleared dental devices.
- ✓ Zirconium oxide is present in all three compositions. This component is responsible for the radiopacity of the products.
- ✓ BIO-C REPAIR ION$^+$, BIO-C REPAIR and BIO-C SEALER ION$^+$ use fumed silica (silicon oxide) as rheometry agent. This component is inert and the percentage of fumed silica used in all devices are highly similar.
- ✓ All materials share the same delivery system (ready-to-use syringe).
- ✓ All materials are provided non-sterile and have comparable setting time, solubility and radiopacity.

BIO-C REPAIR ION$^+$, BIO-C REPAIR and BIO-C SEALER ION$^+$ are available as pre-mixed ready-to-use radiopaque pastes essentially designated for the equivalent dental applications and have comparable physical properties, performance specifications and share specific chemical components as can be seen above.

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

Element	Proposed Device	Predicate Device (K180185)	Reference Device (K190537)	Discuss / Justify the Differences
Trade Name	BIO-C REPAIR ION$^+$	BIO-C REPAIR	BIO-C SEALER ION$^+$	-
Manufacturer	ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A	ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A	ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A	-
Device Description	BIO-C REPAIR ION$^+$ is a ready-to-use bioceramic reparative material for endodontic complications.	BIO-C REPAIR is a ready-to-use bioceramic reparative material for endodontic complications.	BIO-C SEALER ION$^+$ is a ready-to-use bioceramic root canal sealer, suitable for obturation of root canals.	All materials are ready-to-use pastes. BIO-C REPAIR ION$^+$ and BIO-C REPAIR are intended for endodontic complications such as perforations, while BIO-C SEALER ION$^+$ is intended for permanent obturation.
Composition	Calcium and magnesium silicate Silicon oxide Zirconium oxide Dispersing agent Calcium oxide Potassium sulfate Calcium sulfate	Calcium silicates Silicon oxide Zirconium oxide Dispersing agent Calcium oxide Iron oxide	Calcium-magnesium silicate Silicon oxide Zirconium oxide Dispersing agent Potassium sulfate Calcium sulfate	BIO-C REPAIR ION$^+$ and BIO-C SEALER ION$^+$ are mainly composed of calcium-magnesium silicate while BIO-C REPAIR is composed of calcium silicate. They all share the same dispersing, radiopacifier and rheometry agents.
Principle of operation	BIO-C REPAIR ION$^+$ is an insoluble and radiopaque reparative cement which requires the presence of moisture to set and harden. Calcium, magnesium and silicon ions are released in the presence of moisture. The calcium sulfate in presence of moisture produces SO_4^{2-} and Ca^{2+} ions. The sulfate anions (SO_4^{2-}) will combine with H^+ from the water, increasing the concentration of OH^- in the surroundings and the pH of the medium.	BIO-C REPAIR is an insoluble and radiopaque reparative cement which requires the presence of moisture 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.	BIO-C SEALER ION$^+$ is an insoluble and radiopaque root canal sealer which requires the presence of moisture to set and harden. Calcium, magnesium and silicon ions are released in the presence of moisture. The calcium sulfate in presence of moisture produces SO_4^{2-} and Ca^{2+} ions. The sulfate anions (SO_4^{2-}) will combine with H^+ from the water, increasing the concentration of OH^- in the surroundings and the pH of the medium.	All materials are insoluble radiopaque bioceramic cements which require the presence of moisture to set and harden.

Indications for use	Furcation or root perforation treatment via canal; Furcation or root perforation treatment via surgical; Internal reabsorption treatment via canal or surgical; External reabsorption treatment; Retrofilling in parendodontic surgery; Direct and indirect pulp capping; Pulp regeneration; Apexification; Apexogenesis and Pulpotomy.	Furcation or root perforation treatment via canal; Furcation or root perforation treatment via surgical; Internal reabsorption treatment via canal or surgical; External reabsorption treatment; Retrofilling in parendodontic surgery; Direct and indirect pulp capping; Pulp regeneration; Apexification; Apexogenesis and Pulpotomy.	Sealing the root canal of permanent teeth; Internal reabsorption treatment.	BIO-C REPAIR ION$^+$ and BIO-C REPAIR share the same indications for use. BIO-C SEALER ION$^+$ is intended mainly for permanent obturation of the root canal.
Delivery form	Single paste	Single paste	Single paste	Equivalent
Design	Ready-to-use syringe Blunt tips	Ready-to-use syringe Blunt tips	Ready-to-use syringe Disposable Intra Canal tips	BIO-C REPAIR ION$^+$ and BIO-C REPAIR are reparative cements with higher viscosity, therefore, instead applying with intracanal tips they are applied with dental instruments that take the material into the root canal chamber directly on the complication being treated (e.g. perforation). BIO-C SEALER ION$^+$ is a root canal sealer, its fluidity is higher, enabling the application of the material with intracanal tips directly into the root canal chamber in order to permanent fill the main and lateral canals.
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)	Equivalent
Sterile	Non-sterile	Non-sterile	Non-sterile	Equivalent
pH	> 10	12,5	10.5	Equivalent
Setting time	90-120 minutes	90-120 minutes	120-240 minutes	BIO-C REPAIR ION$^+$ and BIO-C REPAIR have a shorter setting time compared to BIO-C SEALER ION$^+$.
Radiopacity	~ 7 mm Al	~ 7 mm Al	≥ 7 mm Al	Equivalent
Biocompatibility	Biocompatible according to ISO 10993-1:2009.	Biocompatible according to ISO 10993-1:2009.	Biocompatible according to ISO 10993-1:2009.	Equivalent

NON-CLINICAL PERFORMANCE TESTING

BIO-C REPAIR ION$^+$ has undergone extensive bench testing. The following bench tests were performed according to ISO 6876:2012 *Dental root canal sealing materials*: setting time, solubility and radiopacity. Additional tests are also performed and incorporated into the product acceptance criteria: injectability, X-ray diffraction, particle size distribution and color determination analyses.

Biological evaluation was performed according to ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process addressing all relevant biological effects. Biocompatibility test results determined that BIO-C REPAIR ION+ is non-sensitizing, non-irritant to oral mucosa of hamsters. Since BIO-C REPAIR ION+ composition is based on principal chemical components in BIO-C REPAIR and BIO-C SEALER ION+, the biocompatibility test data of these devices provide evidence that BIO-C REPAIR ION+ is non-mutagenic, and did not induce genotoxic effects to the bone marrow cells of mice. BIO-C REPAIR ION+ has also met the requirements of absence of acute systemic toxicity after single oral administration and did not demonstrate local and systemic toxic effects when implanted.

CLINICAL PERFORMANCE TESTING

Clinical performance testing was not conducted on the subject device.

CONCLUSION

Based upon a comparison of technology, non-clinical performance testing and similarity in intended use, we concluded that BIO-C REPAIR ION$^+$ is substantially equivalent to the predicate devices.