December 12, 2019

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

Re: K190537
Trade/Device Name: BIO-C Sealer Ion+
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: September 13, 2019
Received: September 13, 2019

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.


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 -S

for Srinivas Nandkumar, Ph.D.
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
Indications for Use

510(k) Number (if known)
K190537

Device Name
BIO-C SEALER ION+

Indications for Use (Describe)
1. Sealing the root canal of permanent teeth;
2. Internal reabsorption treatment;

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 SEALER ION+

K190537

ADMINISTRATIVE INFORMATION

Date prepared: September 13th, 2019

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
International Regulatory Affairs Specialist
juliana.norder@angelus.ind.br

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: BIO-C SEALER ION+
Common Name: Root Canal Filling Resin
Classification Regulation: 21 CFR 872-3820, Class II
Product Code: KIF
Classification Panel: Dental Products Panel
Primary Predicate Device: K172701 BIO-C SEALER (Angelus Indústria de Produtos Odontológicos S/A)
Reference Device: K170175 ENDOSEAL MTA (MARUCHI)
DEVICE DESCRIPTION

BIO-C SEALER ION+ is a ready-to-use injectable bioceramic root canal sealer, developed for sealing the root canals and for the treatment of internal reabsorption.

The product is a single paste provided in a syringe with disposable intracanal tips to be applied directly into the root canal system. BIO-C SEALER 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 canal sealer materials.

PRODUCT PRESENTATION

<table>
<thead>
<tr>
<th>Reference</th>
<th>Product Description</th>
<th>Package Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>3843</td>
<td>BIO-C SEALER ION+</td>
<td>● 4 preloaded syringes with 0.5g each</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● 20 disposable intracanal tips</td>
</tr>
<tr>
<td>3845</td>
<td>BIO-C SEALER ION+</td>
<td>● 1 preloaded syringe with 2g each</td>
</tr>
<tr>
<td></td>
<td></td>
<td>● 5 disposable intracanal tips</td>
</tr>
</tbody>
</table>

INTENDED USE

Sealing the root canals.

INDICATIONS FOR USE

1. Sealing the root canal of permanent teeth;
2. Internal reabsorption treatment.

COMPARISON OF TECHNOLOGY

BIO-C SEALER ION+ and BIO-C SEALER are indicated for equivalent dental applications, have comparable chemical/physical properties and performance specifications and equivalent delivery systems (syringe and disposable intracanal tips). The reference device, ENDOSEAL MTA, contains a chemical component that is found in BIO-C SEALER ION+.

The similarities and differences of BIO-C SEALER ION+ and the predicates are discussed below:
✓ BIO-C SEALER ION+, BIO-C SEALER and ENDOSEAL MTA are mainly composed of calcium silicates. BIO-C SEALER ION+ is composed of calcium and magnesium silicate, and BIO-C SEALER and ENDOSEAL MTA are composed of calcium silicates. Despite the difference between the silicates in the formulations, biocompatibility tests were conducted with the subject device and the results demonstrated that the device is biocompatible.

✓ BIO-C SEALER ION+ and ENDOSEAL MTA uses calcium sulfate as setting agent, whereas BIO-C SEALER sets in the presence of moisture due to the hydration of the calcium silicates.

✓ As BIO-C SEALER ION+ and BIO-C SEALER 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 and is present in several cleared dental devices.

✓ Zirconium oxide is present all compositions. This component is responsible for the radiopacity of the products.

✓ BIO-C SEALER ION+ and BIO-C SEALER use fumed silica (silicon oxide) as rheometry agent. This component is inert and the percentage of fumed silica used in both devices is highly similar.

✓ All materials share the same Delivery System (syringe and disposable intracanal tips).

✓ BIO-C SEALER ION+ and BIO-C SEALER are both provided non-sterile and have comparable setting time, solubility, flow, film thickness and radiopacity.

All materials 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 SEALER ION+ and the predicate devices:
<table>
<thead>
<tr>
<th>Element</th>
<th>Proposed Device (K190537)</th>
<th>Predicate Device (K172701)</th>
<th>Reference Device (K170175)</th>
<th>Discuss / Justify the Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name</td>
<td>BIO-C SEALER ION*</td>
<td>BIO-C SEALER</td>
<td>ENDOSEAL MTA</td>
<td>-</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A</td>
<td>ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A</td>
<td>MARUCHI</td>
<td>-</td>
</tr>
<tr>
<td>Device Description</td>
<td>BIO-C SEALER ION* is a ready-to-use injectable endodontic bioceramic Sealer, suitable for obturation of root canals.</td>
<td>BIO-C SEALER is a ready-to-use injectable endodontic bioceramic Sealer, suitable for obturation of root canals.</td>
<td>ENDOSEAL MTA is an endodontic sealer based on MTA, providing a root canal filling. It is premixed and pre-loaded in a syringe, which allows a complete filling of the entire root canal including accessory and lateral canals.</td>
<td>All three materials are ready-to-use pastes intended for permanent obturation of the root canal. Despite the difference between the silicates in the formulations, biocompatibility tests were conducted with the subject device and the results demonstrated that the device is biocompatible.</td>
</tr>
<tr>
<td>Composition</td>
<td>Calcium and magnesium silicate Zirconium oxide Silicon oxide Potassium sulfate Calcium sulfate Dispersing agent</td>
<td>Calcium silicates Calcium oxide Silicon oxide Zirconium oxide Iron oxide Dispersing agent</td>
<td>Calcium silicates Calcium aluminates Calcium aluminoferrite Zirconium oxide Calcium sulfates Thickening agent</td>
<td>BIO-C SEALER ION*, BIO-C SEALER and ENDOSEAL MTA are mainly composed of calcium silicates. BIO-C SEALER ION* is composed of calcium and magnesium silicate and BIO-C SEALER and ENDOSEAL MTA are composed of calcium silicates. They all share the same radiopacifier, zirconium oxide. ENDOSEAL MTA was also chosen due to the presence of calcium sulfate and to share the same intended use and delivery system (ready-to-use syringe).</td>
</tr>
<tr>
<td>Principle of operation</td>
<td>BIO-C SEALER ION* is an insoluble and radiopaque root canal sealer which requires the presence of water 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.</td>
<td>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.</td>
<td>The inside of the root canal system has high humidity due to residual moisture in the dentinal tubules. MTA solidifies into a hard structure by absorbing the moisture from the surrounding tissue. Calcium hydroxide is produced due to the hydration reaction of the calcium silicates increasing the pH of the medium.</td>
<td>All materials are insoluble radiopaque root canal sealers which require the presence of water to set and harden.</td>
</tr>
<tr>
<td>Indications for use</td>
<td>Sealing the root canal of permanent teeth; Internal reabsorption treatment.</td>
<td>Sealing the root canal of permanent teeth; Internal reabsorption treatment.</td>
<td>Permanent obturation of the root canal following root canal treatment.</td>
<td>Equivalent</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Delivery form</td>
<td>Single paste</td>
<td>Single paste</td>
<td>Single paste</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Design</td>
<td>Syringe Disposable Intra Canal tips</td>
<td>Syringe Disposable Intra Canal tips</td>
<td>Syringe Disposable Intra Canal tips</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Nature of contact</td>
<td>Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (&gt;30 days)</td>
<td>Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (&gt;30 days)</td>
<td>Category: External communicating device Contact: Tissue, bone and dentin Contact Duration: C - Permanent (&gt;30 days)</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Sterile</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Non-sterile</td>
<td>Equivalent</td>
</tr>
<tr>
<td>pH</td>
<td>10.5</td>
<td>12.5</td>
<td>Unknown</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Setting time</td>
<td>120-240 minutes</td>
<td>120-240 minutes</td>
<td>12.31 minutes</td>
<td>All products will set in presence of water, however, according to manufacture, ENDOSEAL MTA presents a faster setting time.</td>
</tr>
<tr>
<td>Radiopacity</td>
<td>$\geq 7$ mm Al</td>
<td>$\geq 7$ mm Al</td>
<td>10.5 mm Al</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Biocompatible according to ISO 10993-1:2009.</td>
<td>Biocompatible according to ISO 10993-1:2009.</td>
<td>-</td>
<td>Equivalent</td>
</tr>
</tbody>
</table>
NON-CLINICAL PERFORMANCE TESTING

BIO-C SEALER 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, flow, film thickness and radiopacity*. Additional tests are also performed and incorporated into the product acceptance criteria: X-ray diffraction analysis, particle size analysis, viscosity and thixotropy tests and color determination analysis.

Biocompatibility tests were conducted with the subject device according to ISO 10993-1:2009 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process* providing evidence that BIO-C SEALER ION+ is non-mutagenic, non-irritant to oral mucosa of hamsters, no sensitizing and has met the requirements of absence of acute systemic toxicity after single oral administration.

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 SEALER ION+ is substantially equivalent to the predicate devices.