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

January 4, 2018

Re: K172701
Trade/Device Name: Bio-C Sealer
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: October 12, 2017
Received: October 12, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*

K172701

Device Name
BIO-C SEALER

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services Food and Drug Administration

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K172701

510(k) Summary

Angelus Indústria de Produtos Odontológicos S/A

BIO-C SEALER

August 28, 2017

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 SEALER
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
Substantial Equivalence:	K080917 iRoot SP (Innovative BioCeramix Inc.)
For specific chemical compositions:	k140247 MTA-FILLAPEX (Angelus Indústria de Produtos Odontológicos S/A) k151047 MTA REPAIR HP cleared under (Angelus Indústria de Produtos Odontológicos S/A)

INTENDED USE

1. Sealing the root canal of permanent teeth;

2. Internal reabsorption treatment.

DEVICE DESCRIPTION

BIO-C SEALER is a ready-to-use injectable endodontic bioceramic sealer, suitable for obturation of root canals.

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 SEALER is substantially equivalent in indications and design principles to the following predicate device:

INNOVATIVE BIOCERAMIX INC., **iRoot SP** cleared under **K080917**

The subject device and the predicate device have the same intended use and have the 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 the technological characteristics do not raise new issues of safety or effectiveness. Even though BIO-C SEALER's main chemical composition is based on iRoot SP, as mentioned above, the additional chemical components in BIO-C SEALER's composition were found in the following predicate devices:

ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A, **MTA-FILLAPEX** cleared under **K140247**

ANGELUS INDÚSTRIA DE PRODUTOS ODONTOLÓGICOS S/A, **MTA REPAIR HP** cleared under **K151047**

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

PERFORMANCE DATA OR NON-CLINICAL EVIDENCE

BIO-C SEALER has undergone extensive bench testing to provide evidence that its physical-chemical properties are substantially equivalent to iRoot SP. Bench tests performed are: flow, setting time, film thickness, solubility and radiopacity.

Both devices have comparable flowability, setting time, film thickness, solubility and radiopacity.

The biocompatibility evaluation provide evidence that the product is non-mutagenic, does not cause an allergenic potential after multiple uses and has a good tolerance.

CONCLUSION

BIO-C SEALER and its predicate device are designated for equivalent dental applications and have comparable chemical and physical properties and performance specifications. Furthermore, BIO-C SEALER 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.