DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 31, 2016

Angelus Industria De Productos Odontologicos
% Lilian Llull
Regulatory Affairs Manager
Techlink International
PO Box 694125
Miami, Florida 33160

Re: K151047
Trade/Device Name: MTA Repair HP
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: July 5, 2016
Received: July 28, 2016

Dear Lilian Llull:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151047

Device Name
MTA Repair HP

Indications for Use *(Describe)*
* Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesions;
* Via canal treatment of root perforation due to internal resorption;
* Surgical treatment of root perforation due to internal resorption;
* Periapical surgery with reverse filling;
* Pulp capping;
* Pulpotomy (removal of affected crown portion of the pulp preserving the vitality and function of the remaining radicular portion)
* Apexogenesis (induction of root development in vital teeth with an inflamed coronal pulp)
* Apexification (induction of formation of a mineralized barrier at the root tip of young permanent teeth with incomplete root development and a necrotic pulp)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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K151047

510(k) Summary

Proprietary Name:	MTA Repair HP
Date of Submission:	August 29, 2016
Submitter:	Angelus Industria de Productos Odontologicos Waldir Landgraf, 101 Londrina, Brazil 86031-3200 TEL – +55 43 2101 3200
Official Contact:	Lilian Llull TechLink International PO Box 694125 Miami, FL 33160 TEL – (305) 974 - 0088
Common Name:	Root Canal Filling Resin
Trade Name:	MTA REPAIR HP
Classification:	Class II
Product Code:	KIF
Classification Panel:	Dental
Regulation Numbers:	21 CFR 872.3820
Substantial Equivalence:	(K112046) MTA-Angelus

Indications for Use:

- Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesions
- Via canal treatment of root perforation due to internal resorption
- Surgical treatment of root perforation due to internal resorption
- Periapical surgery with reserve filling
- Pulp capping
- Pulpotomy (removal of affected crown portion of the pulp preserving the vitality and function of the remaining radicular portion)

* Apexogenesis (induction of root development in vital teeth with an inflamed coronal pulp)
* Apexification (induction of formation of a mineralized barrier at the root tip of young permanent teeth with incomplete root development and a necrotic pulp)

Device Description:

MTA REPAIR HP is an endodontic bioceramic reparative cement with high plasticity, composed of mineral oxides in the form of fine hydrophilic particles. It is indicated for cases of root perforation (canal and furcation), iatrogenic or by caries, root perforation by internal resorption, retrofilling, direct pulp capping, pulpotomy, apexigenesis, and apexification.

The plasticizer Polyvinylpyrrolidone is added in the subject device to improve the plasticity of the mixture powder/liquid, with plasticity being understood as the quality of being easily shaped or molded. Thus, the new formulation of the subject device improves handling and insertion into the dental cavity since the pasted after mixing becomes a molding putty type consistency.

The radiopacifier CaWO4 is also added in the subject device to prevent discoloration of the tooth, since CaWO4 does not reduce when exposed to sunlight, unlike Bi2O3 found in the predicate device. Overall properties noted for the subject device include the following:

- Setting time: MTA Repair HP solidifies upon being maintained in a wet environment after spatulation. The start setting time is approximately 15 minutes.
- Radiopacity: Similar to gutta-percha and more radiopaque than dentin and bone.
- Absence of dental discoloring due to the radiopacifier CaWO4 used.

Device Comparison Table

Element	Proposed Device (K151047)	Predicate Device (K112046)
Trade Name	MTA REPAIR HP	MTA ANGELUS
Device Description	MTA REPAIR HP is an endodontic bioceramic reparative cement with high plasticity, composed of mineral oxides in the form of fine hydrophilic particles. It is indicated for cases of root perforation (canal and furcation), iatrogenic or by caries, root perforation by internal resorption, retrofilling, direct pulp capping, pulpotomy, apexigenesis, and apexification.	MTA Angelus is mineral trioxide aggregate cement used for root repair during endodontic treatment, combining the powder and liquid produces a colloidal gel that solidifies to form a barrier.
Common Name	Resin, Root Canal Filling	Resin, Root Canal Filling
Classification	Root Canal Filling Resin	Root Canal Filling Resin
Class	Class II	Class II
Product Code	KIF	KIF
Indications for Use	* Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesions; * Via canal treatment of root perforation due to internal resorption; * Surgical treatment of root perforation due to internal resorption;	* Treatment of perforations of root canal and furcation caused iatrogenically or by caries lesions * Via canal treatment of root perforation due to internal resorption * Surgical treatment of root perforation due to internal resorption

	* Periapical surgery with reverse filling; * Pulp capping; * Pulpotomy (removal of affected crown portion of the pulp preserving the vitality and function of the remaining radicular portion) * Apexogenesis (induction of root development in vital teeth with an inflamed coronal pulp) * Apexification (induction of formation of a mineralized barrier at the root tip of young permanent teeth with incomplete root development and a necrotic pulp)	* Periapical surgery with reverse filling * Pulp capping * Pulpotomy (removal of affected coronal pulp to preserve vitality of remaining pulp tissue) * Apexogenesis (indication of root development in vital teeth with an inflamed coronal pulp) * Apexification (induction of formation of a mineralized barrier at the root tip of young permanent teeth with incomplete root development and a necrotic pulp)
Biocompatibility	Biocompatible (Biological Evaluation Report)	Biocompatible
Design	Powder (capsule) Liquid (capsule)	Powder (bottle) Liquid (flask)
Shelf Life	3 years	3 years
Standards	ISO 6876:2012 ANS/ADA N° 57 - 2000 ISO 10993-1:2009	ISO 6876:2012 ISO 10993-1:2009

Composition: powder	Tricalcium silicate 3CaO.SiO2 Dicalcium silicate 2CaO.SiO2; Tricalcium aluminate 3CaO. Al2O3; Calcium Oxide CaO; Calcium Tungstate CaWO4;	Tricalcium silicate 3CaO.SiO2; Dicalcium silicate 2CaO.SiO2; Tricalcium aluminate 3CaO. Al2O3; Calcium Oxide CaO; Bismuth Oxide Bi2O3;
Composition: liquid	Distilled water Plasticizer (Polyvinylpyrrolidone)	Distilled water
Packaging	2 capsule system (powder and liquid)	NA
Sterile	NA	NA

Nonclinical Testing:

The subject device features technological characteristics previously cleared in other devices. MTA HP meets the applicable requirements of the following FDA recognized standards:

- ISO 10993-1 Biological evaluation of medical devices-part 1: evaluation and testing.
- ISO 10993.5: 2009 - Biological evaluation for medical devices Tests for cytotoxicity: in vitro methods
- ISO 10993-6: 2007 - Biological evaluation of medical devices - part 6: Tests for local effects after implantation and protocol supplied by the vendor.
- ISO 10993-11: 2006 - Biological evaluation of medical devices - part 11: Tests for systemic toxicity, described in method TOX-052 Rev. 01.
- ANSI/ADA Specification no. 57: Endodontic Sealing Material, 2000.
- ISO 6876:2012 - Dentistry -- Root Canal Sealing Materials

Flow, working time and film thickness ISO 6876 testing is not applicable to root-end filling materials as expected. This is because MTA Repair HP is a root repair material, not a root canal sealer. In this particular situation, ISO 6876:2012 - “Dentistry – Root canal sealing materials” is used as guide to determine properties such as setting time, radiopacity, and solubility. These test results are consistent with the

intended use of root repair materials, because if the material is too fluid there is no possibility to seal the lateral of a root perforation without experiencing the flowing of the cement and, consequently the loss of the material.
Bench test results allowed us to conclude that MTA Repair HP is well suited for its intended use.

Substantial Equivalence:

The subject and the predicate device are substantially equivalent based on identical indications for use, same operating principle and similar material and design. MTA HP and MTA Angelus present the same components except for their radiopacifier. This new radiopacifier agent prevents the discoloration of the tooth, since CaWO4 in the subject device does not reduce when exposed to sunlight, as does Bi2O3 in the predicate device.

MTA HP comes also with a plasticizer in its liquid to improve the plasticity of the material. Physical chemistry and biocompatibility properties of the subject device have not been affected. However, both the substitution of the radiopacifier agent and the addition of the plasticizer into the liquid did not affect the critical properties (setting time, solubility and radiopacity) of MTA REPAIR HP. There is a one minute difference noted in the working time of the subject device, compared to its predicate; however, the time difference does not affect the usability of the subject device.

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate device encompass the same range of physical dimensions, including setting time, solubility, biocompatibility and shelf life. The subject and predicate devices are packaged in similar materials and both are provided nonsterile. Any differences in the technological characteristics do not raise new concerns.

Angelus Industria De Productos Odontologicos has demonstrated that, for the purposes of FDA's regulation of medical devices, MTA Repair HP is substantially equivalent in indications and design principles to its predicate device MTA-Angelus.