K113568

AUG 2 1 2012

510(k) Summary

Angelus Indústria de Produtos Odontológicos S/A

MTA FILLAPEX

August 17, 2012

ADMINISTRATIVE INFORMATION

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Official Contact:	Marco Canonico International Business Director
Representative/Consultant:	Allison C. Komiyama Linda K. Schulz PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 USA Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: akomiyama@paxmed.com lschulz@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	MTA Fillapex
Classification 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

INTENDED USE

MTA Fillapex is a root canal sealer intended for the permanent sealing of root canals and may be used in combination with root canal obturation materials.

DEVICE DESCRIPTION

MTA Fillapex is a mineral trioxide aggregate (MTA) and resin root canal sealer used during endodontic treatment to permanently fill the canal system following debridement and disinfection. It consists of two component pastes that are combined in a dual barrel syringe for ease of dispensing and consistent dosage. Being hydrophilic in nature, MTA Fillapex is desirable as a root filling material because an isolated dry field is not necessary for use. Moisture does not negatively affect the sealing ability and is required for proper setting. It is used in combination with gutta-percha or silver points during root canal obturation. The device is provided non-sterile.

EQUIVALENCE TO MARKETED DEVICE

K112046 - Angelus Industria de Produtos Odontologicos S/A, MTA Angelus,
K080203 - Dentsply International, MTA ROOT CANAL SEALER,
K820215 - Dentsply International, Improved Dycal,
K010940 - Sybron Dental Specialties, Inc.,Sealapex 4,
K102163 - Sybron Dental Specialties, Inc., RealSeal XT Sealer,
K893794 - Williams Dental Co. Apexit, and
K063237 - Bisco, Inc., TheraCal LC.

The subject device is compositionally substantially equivalent to the predicate devices listed above. The design of the subject device (base/catalyst, two paste system) is similar to the devices cleared in K820215, K010940, K102163, and K893794. The intended use of the subject device is the same as the devices cleared in K112046, K080203, K010940, K102163, and K893794. The subject and predicate devices have the same/similar technological characteristics.

NON-CLINICAL TESTING

Biocompatibility data were provided to demonstrate substantial equivalence to the predicate devices. Side-by-side cytotoxicity testing (conforming to ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for* in vitro *cytotoxicity*) was performed that compared the subject device with predicates.

Performance testing that conformed to the protocols and recommended values described in ISO 6876 *Dental root canal sealing materials* was performed. Test reports included flow, working time, setting time, film thickness, dimensional change, solubility and radiopacity.

CONCLUSION

The conclusions drawn from the substantial equivalence discussion as well as non-clinical tests demonstrate that the device is substantially equivalent to the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Angelus Indústria de Produtos Odontológicos S/A
C/O Ms. Linda K. Schulz
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

AUG 2 1 2012

Re: K113568
Trade/Device Name: MTA - Fillapex
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: II
Product Code: KIF
Dated: August 13, 2012
Received: August 14, 2012

Dear Ms. Schulz:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113568

Indications for Use

510(k) Number: _____

Device Name: MTA-FILLAPEX

Indications for Use:

MTA-FILLAPEX is a root canal sealer intended for the permanent sealing of root canals and may be used in combination with root canal obturation materials.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113568

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)