510(k) Summary

Angelus Indústria de Produtos Odontológicos S/A

MTA Angelus
K112046

December 27, 2011

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:	Marco Canonico International Business Director
Representative/Consultant:	Linda K. Schulz Kevin A. Thomas PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	MTA Angelus
Classification Name:	Root Canal Filling Resin
Classification Regulations:	21 CFR 872.3820, Class II
Product Code:	KIF
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

K112046

INTENDED 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 reverse filling
- Pulp capping
- Pulpotomy (removal of affected coronal pulp to preserve vitality of remaining pulp tissue)
- 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 Angelus is a 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.

EQUIVALENCE TO MARKETED DEVICE

Angelus Indústria de Produtos Odontológicos S/A demonstrated that, for the purposes of FDA's regulation of medical devices, MTA Angelus is substantially equivalent in indications and design principles to the following predicate devices:

DENTSPLY International, MTA Advanced Material cleared under K073218 and
DENTSPLY International, White MTA Material cleared under K011009.
DENTSPLY International, MTA Root Canal Sealer K080203

The subject device and the predicate devices have the same or similar intended use and have the same technological characteristics and are made of the same or 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 efficacy.

Performance testing was conducted for setting time, solubility, radiopacity and dimensional changes to demonstrate substantial equivalence and included methods described in ISO 6876 *Dental Root Canal Sealing Materials.*

Overall, MTA Angelus has the following similarities to the predicate devices:

- has the same or similar intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging.

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 Industria de Produtos Odontologicos S/A
C/O Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

JAN - 6 2012

Re: K112046
Trade/Device Name: MTA Angelus
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: December 27, 2011
Received: December 28, 2011

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

Indications for Use

510(k) Number: _____

Device Name: 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 reverse filling
- Pulp capping
- Pulpotomy (removal of affected coronal pulp to preserve vitality of remaining pulp tissue)
- 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)

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)

Page 1 of __

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

510(k) Number: K112046