DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 26,2015

Dentsply International Inc.
Helen Lewis
Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17401

Re: K142178
Trade/Device Name: Pro Root MTA
Regulation Number: 21 CFR 872.3820
Regulation Name:
Regulatory Class: II
Product Code: KIF
Dated: November 24, 2014
Received: November 28, 2014

Dear Ms. Helen Lewis:

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" (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 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,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142178

Device Name(s): ProRoot MTA White/Gray (Pediatric Pulpotomy)

Indications for Use:

- A root end filling material
- For the repair of repair of root canals as an apical plug during apexification
- For repair of root perforations during root canal therapy or as a consequence of internal resorption
- As a pulp capping material
- Pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations

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)

SECTION 5. 510(k) SUMMARY
for
ProRoot MTA White/Gray (Pediatric Pulpotomy)

5.1 Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street, Suite 60
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: 04 August 2014

5.2 Device Name:

- Proprietary Name: ProRoot MTA White
  ProRoot MTA Gray
- Classification Name: Resin, root canal filling
- CFR Number: 872.3850
- Device Class: II
- Product Code: KIF

5.3 Predicate Devices:

Predicate Device Name	510(k)	S.E. Date	Company Name
White MTA Material	K011009	May 2, 2001	DENTSPLY International, Inc.
MTA Material II	K981260	July 31, 1998	DENTSPLY International, Inc.

5.4 Description of Device:

The proposed ProRoot MTA White/Gray (Pediatric Pulpotomy) is identical to the predicates White MTA Material, K011009 and MTA Material II, K981620.

ProRoot MTA White and ProRoot MTA Gray is a powder consisting of fine hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.

5.5 Indications for Use:

- A root end filling material
- For the repair of repair of root canals as an apical plug during apexification
- For repair of root perforations during root canal therapy or as a consequence of internal resorption
- As a pulp capping material
- Pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations

5.6 Substantial Equivalence:

Technological Characteristics.

	Predicate Device White MTA Material K011009	**Predicate Device** MTA Material II K981620	**Proposed Device** ProRoot MTA White/Gray (Pediatric Pulpotomy)
Indications for Use	• Repair of root perforation during root canal therapy (endodontic therapy), or as a consequence of internal resorption; • Repair of root canals as an apical plug during apexification; • Root end filling material; and • Pulp capping material	• A root end filling material.	• A root end filling material • For the repair of repair of root canals as an apical plug during apexification • For repair of root perforations during root canal therapy or as a consequence of internal resorption • As a pulp capping material • Pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations

Features	ProRoot MTA White and ProRoot MTA Gray is a powder consisting of fine hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.	ProRoot MTA White and ProRoot MTA Gray is a powder consisting of fine hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.	ProRoot MTA White and ProRoot MTA Gray is a powder consisting of fine hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.

5.7 Non-Clinical Performance Data:

The quality requirements for the devices have not changed as a result of this filing. Only the proposed Indications for Use for the ProRoot MTA White/Gray (Pediatric Pulpotomy) have been modified as compared to the predicates White MTA Material, K011009 and MTA Material II, K981620. The results of performance testing and biocompatibility testing conducted for the predicate devices, White MTA Material (K011009) and MTA Material II (K981620) are valid, therefore, no additional performance testing or biocompatibility testing has been performed.

5.8 Clinical Performance Data:

ProRoot MTA White and ProRoot MTA Gray have been sold by DENTSPLY International and its predecessors since February 10, 1997 and have been in use as a dental repair material since that time. ProRoot MTA White/Gray (Pediatric Pulpotomy) have been studied extensively in technical literature by dental professionals[1], and based on the completed studies (pulpotomy in 171 pediatric patients covering 408 primary teeth), it is appropriate to add pulpotomy of primary teeth as an indication for use in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations for ProRoot MTA White and ProRoot MTA Gray.

Review of relevant clinical data available in independently reviewed medical literature and the consideration of clinical use is germane when assessing the safety and effectiveness of the device when adding a primary indication directed

[1] Srinivasan, V, *et al* "Mineral trioxide aggregate in paediatric dentistry" **International Journal of Paediatric Dentistry**, 19:34-47, 2009.

at the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations.

5.9 Conclusion as to Substantial Equivalence

The ProRoot MTA White and ProRoot MTA Gray material covered by this application are substantially equivalent to the predicate devices, as they are identical to the predicate devices and the purpose of this application is only to define a new indication for use for a special population of patients [child (ages >2-12 years) and adolescent (ages >12-21 years)].[2]

[2] Guidance for Industry and FDA Staff "Premarket Assessment of Pediatric Medical Devices" March 14, 2014