K140955

Avalon Biomed Inc.™

Carolyn Primus, President

JUN 11 2014

April 4, 2014

510(k) Summary

per 21CFR807.92

CONTACT:

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DATE PREPARED: May 23, 2014

TRADE OR PROPRIETARY NAME: MTA2.1 MATERIAL

CLASSIFICATION NAME: Root Canal Filling Resin 872.3820

PREDICATE DEVICE: K122892, MTA2 ROOT AND PULP MATERIALS

DEVICE DESCRIPTION: The MTA2.1 MATERIAL is designed and developed for dental clinicians to use in contact with vital pulp tissue and periradicular tissue, including sealing and obturation of root canals. This material
can be used for dental procedures contacting pulpal or periradicular tissue such as: Pulp capping, Cavity lining, Base material in a cavity, Pulpotomies, Root-end filling, Apexification, Perforation repair, Root resorption, and Obturation (pulpectomy) in primary or secondary teeth.

The dentist will mix the powder and water-based gel and place the mixed MTA2.1 MATERIAL into the space created by the procedure. The procedure may be part of caries treatment, root canal treatment, or periapical surgery. These procedures are performed on primary and secondary dentition and are color stable over time. MTA2.1 MATERIAL is tinted yellow, pink and gray.

INTENDED USE: The MTA2.1 MATERIAL is intended for use for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

TECHNOLOGICAL CHARACTERISTICS: The MTA2.1 MATERIAL is primarily hydraulic tricalcium silicate powder that is substantially similar to the MTA2 ROOT AND PULP

MATERIAL (K122892). The tricalcium silicate powders are known to set with water into a hard substance, containing calcium hydroxide dispersed among the hydrated particles of tricalcium silicates. Both materials are radiopaque.

COMPARISONS TO PREDICATE: We believe the MTA2.1 MATERIAL is substantially equivalent to the MTA2 ROOT AND PULP MATERIAL (K122892) when used for contact with pulp tissue and periapical tissue, and as a root canal sealer.

The only modification to the predicate MTA2 ROOT AND PULP MATERIAL (K122892) is a change in a radiopacity component and inorganic pigments. This modification does not affect indications for use or technology. It does not raise any new questions of safety or effectiveness.

Similarities: The predicate and the MTA2.1 MATERIAL are based on an inorganic powder composed of primarily tricalcium silicate, dicalcium silicate, and a radiopaque inorganic oxide. The predicates and the MTA2 ROOT AND PULP MATERIALS rely on water to hydrate the calcium silicate phases, and cause setting into a hard substance containing hydrated silicates and some calcium hydroxide.

Both the MTA2.1 MATERIAL and the predicate are used in root canals or on vital pulp tissue. Both the MTA2.1 MATERIAL and the predicate MTA2 ROOT AND PULP MATERIALS are used for sealing and obturation of root canals. The MTA2.1 MATERIAL and the predicate MTA2 ROOT AND PULP MATERIALS are similar because both kits contain the same gel.

The new and predicate materials had similar compositions, radiopacity, film thickness, flow and compressive strengths, when mixed at similar powder to liquid/gel ratios. Both MTA2.1 MATERIAL and the predicate material induce the precipitation of hydroxyapatite crystals in synthetic body fluid because of the tricalcium silicate powder component.

Differences: MTA2.1 material will be slightly different in color than the MTA2 ROOT AND PULP MATERIALS, which are white and gray in color. Different radiopaque and pigment powders are included in MTA2.1 than in the predicate. MTA2.1 material will be more stable to potential discoloration over time.

NON-CLINICAL PERFORMANCE: As part of design validation, MTA2.1 MATERIAL meet the ADA 57 standard for radiopacity, solubility, dimensional stability, film thickness, and flow. The ADA 57 tests were also performed to measure the working time and setting time of MTA2.1 compared to the predicates. Tests for compressive strength and leaching of arsenic and lead were performed to shown conformance to ISO 9917. Washout tests confirm the stability of the material. Discoloration tests confirm the color stability of the material.

The MTA2.1 MATERIAL was evaluated for biocompatibility with its gel in cytotoxicity test as part of design validation.

CLINICAL PERFORMANCE: No clinical tests were performed in the development of the MTA2.1 MATERIAL.

SUBSTANTIAL EQUIVALENCE: Bench testing was performed as part of design validation to demonstrate continued conformance with the requirements were achieved to conform to the FDA recognized standards ADA 57 and appropriate requirements of ISO 9917.

We believe that the performance data provided herein demonstrate that MTA2.1 ROOT AND PULP MATERIALS are substantially equivalent to the predicate MTA2 (K122892) in design, principle of performance, technology, and composition. We believe the MTA2.1 MATERIAL performs as well as or better than the predicate device.

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

June 11, 2014

Avalon Biomed Incorporated
Dr. Carolyn Primus
President
7282 55th Avenue East #227
Bradenton, FL 34203

Re: K140955
Trade/Device Name: MTA2.1 Material
Regulation Number: 21 CFR 872.3820
Regulation Name: Resin, Root Canal Filling
Regulatory Class: II
Product Code: KIF
Dated: May 23, 2014
Received: May 30, 2014

Dear Dr. Primus:

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 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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Enclosure

Indications for Use

510(k) Number (if known): K140955

Device Name: MTA2.1 MATERIAL

Indications For Use:

The MTA2.1 MATERIAL is indicated for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

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