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

September 1, 2016

Avalon Biomed Inc.
Carolyn Primus
President
1912 44th Ave E
Bradenton, Florida 34203

Re: K161239
Trade/Device Name: Mta2.2 Material
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: May 31, 2016
Received: June 7, 2016

Dear Carolyn 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 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)*
K16

Device Name
MTA 2.2

Indications for Use *(Describe)*
The MTA2.2 MATERIAL is indicated for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

per 21CFR807.92

I. SUBMITTER

DATE PREPARED: April 24, 2016
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II. DEVICE

TRADE OR PROPRIETARY NAME: MTA2.2 MATERIAL
CLASSIFICATION NAME: Root Canal Filling Resin 872.3820 class II
PREDICATE DEVICE: K140955, MTA2.1 ROOT AND PULP MATERIALS

III. PREDICATE DEVICES

MTA 2.2 MATERIAL IS substantially equivalent to the following predicate devices with respect to intended use, indications for use, materials, technological characteristics, and device design. MTA2.2 MATERIAL has been slightly modified from MTA2.1 MATERIAL to allow for more radiopacity and slightly different handling characteristics. The predicate has not been subject to a recall.

510(k) #	Device	Manufacturer
K140955	MTA2.1	Avalon Biomed Inc

IV. DEVICE DESCRIPTION:

The MTA2.2 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 of MTA2.2 and place the mixed MTA2.2 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. MTA2.2 MATERIAL is tinted yellow, pink and gray.

V. INDICATIONS FOR USE:

The MTA2.2 MATERIAL is intended for use for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals This is identical to the predicate K140955, MTA 2.1 MATERIAL.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

TECHNOLOGICAL CHARACTERISTICS: The MTA2.2 MATERIAL is primarily hydraulic tri/dicalcium silicate powder as is the MTA2.1 MATERIAL (K140955). The tri/dicalcium silicate powders are known to set with water into a hard substance, containing calcium hydroxide dispersed among the hydrated particles of tri/dicalcium silicates. Both materials are radiopaque.

COMPARISONS TO PREDICATE: We believe the MTA2.2 MATERIAL is substantially equivalent to the MTA2.1 ROOT AND PULP MATERIAL (K140955) when used for contact with pulp tissue and periapical tissue, and as a root canal sealer.

The modification to the predicate MTA2.1 ROOT AND PULP MATERIAL (K140955) is an increase in the radiopaque component. This modification does not affect indications for use or technology. It does not raise any new questions of safety or effectiveness. The water-based gel has a slightly modified composition.

Similarities: The predicate MTA2.1 ROOT AND PULP MATERIALS and the modified MTA2.2 MATERIAL are based on the same inorganic powder composed of primarily tricalcium silicate, dicalcium silicate, and a radiopaque inorganic oxide. The predicate and the MTA2.2 ROOT AND PULP MATERIAL 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 MTA2.2 MATERIAL and the predicate MTA2.1 ROOT AND PULP MATERIALS are used in root canals or on vital pulp tissue. Both the MTA2.2 MATERIAL and the predicate MTA2.1 ROOT AND PULP MATERIALS are used for sealing and obturation of root canals. Both the MTA2.2 MATERIAL and the predicate MTA2.1 ROOT AND PULP MATERIALS are suitable for use in primary dentition without causing long-term discoloration. The MTA2.2 MATERIAL and the predicate MTA2 ROOT AND PULP MATERIALS are similar because both kits contain the same gel.

The new and predicate materials have similar compositions, film thickness, flow and compressive strengths, when mixed at similar powder to liquid/gel ratios. Both MTA2.2 MATERIAL and the predicate MTA2.1 ROOT AND PULP MATERIALS induce the precipitation of hydroxyapatite crystals in synthetic body fluid because of the tricalcium silicate powder component.

Differences: MTA2.2 MATERIAL is more radiopaque than MTA2.1 ROOT AND PULP MATERIALS. MTA2.2 material may be slightly different in color than the MTA2.1 ROOT AND PULP MATERIALS, although the inorganic pigments are the same.

We believe that the performance data provided herein demonstrate that MTA2.2 ROOT AND PULP MATERIALS are substantially equivalent to the predicate MTA2.1 (K140955) in design, principle of performance, technology, and composition. We believe the MTA2.2 MATERIAL performs as well as or better than the predicate device.

Table VI-1: Comparison of Subject MTA2.2 to Predicate (MTA2.1 K140955)

	Subject Device **MTA2.2**	**Predicate Device** **MTA2.1**
510(k) Number	K16	K140955
Manufacturer	Avalon Biomed Inc.	Avalon Biomed Inc.
Device Name	MTA2.2	MTA2.1
Description	Root canal filling resin	Root canal filling resin
Medical Specialty	Dental	Dental
Product Code	KIF	KIF
Reg Number	872.3820	872.3820
Class	2	2
Materials	Powder: Tri/dicalcium silicate with radiopaque additive. Liquid: Water-based gel	Powder: Tri/dicalcium silicate with radiopaque additive. Liquid: Water-based gel
Design	Powder and gel to be mixed prior to use by clinician.	Powder and gel to be mixed prior to use by clinician.
	More radiopaque	Radiopaque
	Water-based-gel	Water-based gel
Indications for Use	The MTA2.2 MATERIAL is indicated for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals	The MTA2.1 MATERIAL is indicated for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals
Sterility	Non-Sterile	Non-Sterile
Utility	Single-use Only	Single-use Only

VII. PERFORMANCE DATA

NON-CLINICAL PERFORMANCE: 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. As part of design validation, MTA2.2 MATERIAL met 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 MTA2.2 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.

MTA2.2 conforms to the recognized consensus standards:

- ISO 6876: Endodontic sealing materials
- ADA 57: Endodontic Sealing Material

MTA2.2 was test for conformance to these standards for flow, film thickness, solubility, setting time, working time, and radiopacity.

The MTA2.2 MATERIAL was evaluated for biocompatibility with its gel in cytotoxicity test as part of design validation.

CLINICAL PERFORMANCE: No animal clinical tests were performed in the development of the MTA2.2 MATERIAL.

All of the components found in the MTA2.2 have been used in legally marketed devices and were found safe for dental use. MTA2.2 material has a similar composition to the predicate device.

VIII. CONCLUSIONS

No substantial differences in terms of composition and mechanical properties are known between the MTA2.2 and the predicate device. The difference in the modified material is the addition of additional radiopaque component and a modification of the gel. The change does not raise any new issues of safety and effectiveness. The technological characteristics, safety, effectiveness and materials are identical to MTA 2.1 (K140955). Therefore, we believe that the information provided herein demonstrates that the MTA2.2 is substantially equivalent to the predicate devices in design, principles of performance, and intended use.