NuSmile, LTD.
Angie Beyer
Regulatory Affairs & Quality Assurance Specialist
3315 W 12th Street
Houston, Texas 77008

January 11, 2019

Re: K181917
Trade/Device Name: MTA2.3 Root & Pulp Materials
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: Class II
Product Code: KIF
Dated: October 24, 2018
Received: October 25, 2018

Dear Angie Beyer:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,
Mary S. Runner -S3
Digitally signed by Mary S. Runner -S3
Date: 2019.01.11 10:59:11 -05'00'
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181917

Device Name
MTA2.3 ROOT & PULP MATERIALS

Indications for Use *(Describe)*
The MTA2.3 ROOT & PULP MATERIALS are 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.

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K181917

510(k) Summary

per 21CFR807.92 & 807.93

I. SUBMITTER

DATE PREPARED: June 30, 2018

PREPARER:
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II. DEVICE

TRADE OR PROPRIETARY NAME:	MTA2.3 ROOT & PULP MATERIALS
CLASSIFICATION NAME:	Root Canal Filling Resin, 872.3820
PREDICATE DEVICE:	K161239, MTA2.2 material

III. PREDICATE DEVICES

MTA2.3 ROOT & PULP MATERIALS are substantially equivalent to the following predicate devices with respect to intended use, indications for use, materials, technological characteristics, and device design.

510(k) #	Device	Manufacturer
K161239	MTA2.2	Avalon Biomed Inc.*, *assets of Avalon Biomed were acquired by NuSmile, Ltd. (2016), including 510(k)s

The predicate has not been subject to a recall.

MTA2.3 ROOT & PULP MATERIALS have been modified from MTA2.2 MATERIAL to allow for more radiopacity and varied clinical handling characteristics.

IV. DEVICE DESCRIPTION:

The MTA2.3 ROOT & PULP MATERIALS are designed and developed for dental clinicians to use in contact with vital pulp tissue and periradicular tissue, including sealing and obturation of root canals. The materials 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) including root canal sealing.

The mechanism of action is for the subject and predicate devices is setting of the inorganic, ceramic cement in the presence of the water-based body fluids present in teeth.

MTA2.3 ROOT & PULP MATERIALS were developed in 2 forms (designs): powder with water-based gel, and pastes. The dentist may choose to mix the powder and water-based gel of MTA2.3 (design 1), or choose to use a paste form of MTA2.3 (design 2). The MTA2.3 ROOT & PULP MATERIALS are placed in the space created by the procedure and set i*n vivo*. The procedure may be part of caries treatment, root canal treatment, or periapical surgery. Such procedures are performed on primary and secondary dentition. MTA2.3 ROOT & PULP MATERIALS may be white or tinted yellow, pink or gray. MTA2.3 ROOT & PULP MATERIALS are color stable over time.

V. INDICATIONS FOR USE:
The MTA2.3 ROOT & PULP MATERIALS are intended for dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

These indications are identical to the predicate K161239, MTA2.2 MATERIAL.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

TECHNOLOGICAL CHARACTERISTICS: The MTA2.3 ROOT & PULP MATERIALS are primarily hydraulic ceramic powders, as is the MTA2.2 MATERIAL (K161239). The ceramic powders set *in vivo* in contact with body fluids. The technology is unchanged.

The hydrophilic ceramic powders are known to set with water into a hard substance, containing a high pH, calcium hydroxide reaction product, dispersed among the hydrated particles of tri/dicalcium silicates. Both the predicate and the subject materials are radiopaque and contain the same ceramic oxide for radiopacity.

COMPARISONS TO PREDICATE: We believe the MTA2.3 ROOT & PULP MATERIALS are substantially equivalent to the MTA2.2 material (K161239) when used for contact with pulp tissue and periapical tissue, as well as obturation and sealing of root canals.

The modifications to the predicate MTA2.2 material (K161239) are an increase in the radiopaque component, and modified liquids for the convenience delivery into the tooth by the clinician. These modifications do not change the intended use, indications for use, or technological characteristics. The modifications do not raise any new questions of safety or effectiveness.

Similarities: The predicate MTA2.2 material and the modified MTA2.3 ROOT & PULP MATERIALS are based on the inorganic ceramic powders composed of primarily tricalcium silicate, dicalcium silicate, and tantalite for radiopacity. The predicate and the MTA2.3 ROOT & PULP MATERIALS rely on water-based fluids in the body to hydrate the hydraulic ceramic phases, and cause setting into a hard substance containing hydrated silicates and hydroxides. MTA2.3 ROOT & PULP MATERIALS may contain the same inorganic ceramic pigments, at minor levels, as were cleared for MTA2.2 materials.

Both the MTA2.3 ROOT & PULP MATERIALS and the predicate MTA2.2 material are similar because they are:

- ceramic cements,
- used in root canals or on vital pulp tissue
- used for sealing and obturation of root canals
- suitable for use in primary dentition for pulpal treatment
- are based on ceramic powders that set with water
- are radiopaque
- do not discolor
- set in vivo with contact with water-based body fluids.

The new and predicate materials have similar compositions and properties. Both MTA2.3 ROOT & PULP MATERIALS and the predicate MTA2.2 material create a high pH environment, which induces the precipitation of hydroxyapatite-like crystals in synthetic body fluid when the tri/dicalcium silicate powder component is hydrated.

Differences: MTA2.3 ROOT & PULP MATERIALS are more radiopaque than MTA2.2 material.

MTA2.3 ROOT & PULP MATERIALS may be packaged with a modified water-based liquid for mixing, or premixed with an organic liquid.

The similarities and differences are summarized in Table VI-1. Two design modifications are being submitted. The two designs are described in Table VI-2.

Table VI-1: Comparison of Subject MTA2.3 to Predicate (MTA2.2 Materials, K161239)

	Predicate Device **MTA2.2 Material**	**Subject Device** **MTA2.3 ROOT & PULP MATERIALS**
510(k) Number	K161239	K18XXXX
Manufacturer	Avalon Biomed Inc.	NuSmile, Ltd.[1]
Device Name	MTA2.2	MTA2.3
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
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 MTA2.3 ROOT & PULP MATERIALS are 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- for each dose dispensed from a multi-use container	Single-use Only- for each dose dispensed from a multi-use container
Materials	Powder: Tri/dicalcium silicate with tantalum oxide. Liquid: Water-based gel with polymers.	Powder: Tri/dicalcium silicate with more tantalum oxide. One design has additional ceramic powders. Liquid: Water-based gel with thickeners & proprietary additives OR an organic liquid as described for each design.

Table VI-2: Description of Predicate (MTA2.2 K161239) and Subject MTA2.3 Designs

Predicate design	**Powder based on water-setting cements** **Radiopaque with tantalite** **Water-based gel containing polymers** **Powder and gel to be mixed prior to use by clinician**
Design modification-1	Powder contains same components as predicate with more tantalite Water-based gel with more thickening agents & other additives than predicate Powder and gel to be mixed prior to use by clinician
Design modification-2	Powder contains same components as predicate with more tantalite. Powder contains additional ceramic additives for handling. Powder supplied as a paste, or a powder to the clinician.

[1] NuSmile, Ltd. purchased the assets of Avalon Biomed Inc. in 2016, including the prior 510(k) licenses.

VII. PERFORMANCE DATA

NON-CLINICAL PERFORMANCE: Bench testing of the physical properties of the MTA2.3 ROOT AND PULP MATERIALS was performed to verify conformance to ISO 6876, ADA 57, and ISO 9917-1, as they apply. We believe that the performance data provided herein demonstrate that MTA2.3 ROOT AND PULP MATERIALS are substantially equivalent to the predicate MTA2.2 material (K161239) in design, principle of performance, technology, and composition. We believe the MTA2.3 ROOT & PULP MATERIALS perform as well as or better than the predicate device.

As part of design validation, MTA2.3 ROOT & PULP MATERIALS met the ISO 6876 standard for radiopacity, solubility, dimensional stability, film thickness, and flow. The ISO 6876 tests were also performed to measure the working time and setting time of MTA2.3 ROOT & PULP MATERIALS. Tests for arsenic and lead were performed to ensure conformance to ISO 9917-1 requirements. We believe that the performance data provided herein demonstrate that MTA2.3 ROOT AND PULP MATERIALS are substantially equivalent to the predicate MTA2.2 material (K161239) in design, principle of performance, technology, and composition. We believe the MTA2.3 ROOT & PULP MATERIALS perform as well as or better than the predicate device.

BIOCOMPATIBILITY: The MTA2.3 ROOT & PULP MATERIALS were evaluated for biocompatibility as part of design validation. The materials were not cytotoxic. See Appendix C and Section 16.

CLINICAL PERFORMANCE: No animal or human clinical tests were performed in the development of the MTA2.3 ROOT & PULP MATERIALS.

MTA2.3 ROOT & PULP MATERIALS have a similar composition to the predicate device. All of the components found in the MTA2.3 ROOT & PULP MATERIALS have been used in legally marketed devices.

VIII. CONCLUSIONS

No substantial differences in terms of technology are known between the MTA2.3 ROOT & PULP MATERIALS and the predicate device. The main difference in the modified material is additional radiopaque component. Secondary differences include a modified gel for one design, and use of an organic liquid in the second design. The compositional changes do not raise any new issues of risk, safety and effectiveness. Therefore, we believe that the information provided herein demonstrates that the MTA2.3 ROOT & PULP MATERIALS are substantially equivalent to the predicate device in technology, design, principles of performance, and intended use.