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

tYDS Biotech Incorporation
Liang-Yu Chang
Project Manager
Rm. 7, 2F., No. 229, Fuxing 2nd Rd.
Zhubei City, Hsinchu County 302
TAIWAN (R.O.C.)

April 25, 2017

Re: K162661
Trade/Device Name: SavDen™ MTA Root Canal Filling Materials
Regulation Number: 21 CFR 872.3820
Regulation Name: Root canal filling resin
Regulatory Class: Class II
Product Code: KIF
Dated: February 24, 2017
Received: February 27, 2017

Dear Liang-Yu Chang:

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,

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

Change Control Table, Change History

Change Control Table

Version	Document Author	Document Approver	Date Approved
1.00	Name, Title, Office	Name, Title, Office	MM/DD/YYYY

Complete Change Control Table (all versions) retained in SWIFT Docs.

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)*

Device Name
SavDenTM MTA Root Canal Filling Materials

Indications for Use *(Describe)*
- A root end filling material.
- For the 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: April 25, 2017

5.3 Submitter:

tYDS Biotech Incorporation
Address: Rm. 7, 2F, No.229, Fuxing 2nd Rd., Zhubei City, Hsinchu County 302, Taiwan (R.O.C.)
Phone: +886-3-6589590
Fax: +886-2-27362295
Contact: Liang-Yu Chang (alex627324@gmail.com)

5.4 Identification of the Device:

Proprietary/Trade name:	SavDen™ MTA Root Canal Filling Materials
Regulation Description:	Root canal filling resin.
Review Panel:	Dental
Regulation Number:	872.3820
Device Class:	II
Product Code:	KIF

5.4 Identification of the Predicate Device:

Predicate Device Name:	ProRoot MTA White/Gray (Pediatric Pulpotomy)
Manufacturer:	Dentsply International Inc.
Regulation number:	872.3820
Device Class:	II
Product Code:	KIF
510(k) Number:	K142178

5.5 Intended Use/ Indications for Use of the Device

- A root end filling material.
- For the 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 Device Description

SavDen™ MTA powder consists of fine, hydrophilic particles that set in the presence of water. Hydration of the powder creates a colloidal gel that is solidified to form an impermeable barrier that fully cures over a four-week period.

5.7 Non-clinical Testing

A series of safety and performance tests were conducted on the proposed device, SavDen™ MTA Root Canal Filling Materials.

- Shelf life test
- Biocompatibility test
  - In Vitro Cytotoxicity Test – MTT Assay
  - Skin Sensitization Study (Maximization Test)
  - White Rabbit Intracutaneous Irritation Test
  - Acute Systemic Toxicity Study

- White Rabbit Pyrogen Test
- Salmonella Reverse Mutation Test
- In Vitro Mammalian Cell Gene Mutation Test
- In Vitro Mammalian Chromosomal Aberration Test
- Muscle Implant Study

- Bench Test
  - Setting time
  - Solubility and disintegration
  - Radio-opacity
  - pH test
  - X-ray diffraction testing
- Animal Test

All the test results demonstrate that SavDen™ MTA Root Canal Filling Materials meets the requirements of its pre-defined acceptance criteria, and is substally equivalent to the predicate device.

5.8 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.9 Substantial Equivalence Determination

The SavDen™ MTA Root Canal Filling Materials has the same intended use, principle of operation and technological characteristics with the predicate device (K142178). A series of tests were performed and demonstrated substantial equivalence between the proposed and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Proposed device	Predicate device
Proprietary Name	SavDen™ MTA Root Canal Filling Materials	ProRoot MTA White/Gray (Pediatric Pulpotomy)

510(k) No.	—	K142178
Intended Use	- A root end filling material. - For the 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.	- A root end filling material. - For the 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.
Principle of Operation	SavDen™ MTA Root Canal Filling Materials is a powder consisting of fine, hydrophilic particles that set in the presence of water. Hydration of the powder creates a colloidal gel that solidifies (Calcium silicate hydrate, C-S-H) to form an impermeable barrier.	ProRoot MTA White/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.
Component	Powder: Calcium silicate, Bismuth (III) oxide Liquid: Sterilized water	Powder: Portland cement, Bismuth (III) oxide Liquid: Pure water
Materials Ratio (wt %)	Calcium silicate 80% Bismuth (III) oxide (Bi_2O_3) 20%	Portland cement 80% Bismuth (III) oxide (Bi_2O_3) 20%
Setting Ratio	Liquid to powder ratio: [L]/[P] = 1/4	N/A *
Solubility	Not exceed 3% by mass	Not exceed 3% by mass

Radio-opacity	> 3 mmAl	> 3 mmAl
pH Value of Extractable Matters	pH 12.4 ± 0.5	pH 12.4 ± 0.5
Product Shelf Life	2 years	2 years

* The predicate device does not disclose the setting ratio. In general, the setting ratio for the predicate device used by dentists is 0.3~0.4 g powder per 0.1 ml liquid.

5.10 Similarity and Differences

The difference between the proposed device and predicate device are component and setting ratio. We define a proposed ratio of 0.4 g powder per 0.1 ml liquid for the proposed device. But the predicate device does not disclose the setting ratio. In general, the setting ratio for the predicate device used by dentists is 0.3~0.4 g powder per 0.1 ml liquid.

We conducted the X-ray diffraction testing using X-Ray Diffraction to analysis the chemical composition of the proposed and predicate device. XRD analysis results revealed the substantial equivalence in the chemical composition of the proposed and predicate device.

The other properties of these two devices are the same. The proposed device has been conducted on safety and performance tests, and the results complied with the test requests. Therefore, the difference between the proposed and the predicate device did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate device in safety and performance claims.

5.11 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that SavDen™ MTA Root Canal Filling Materials is substantially equivalent to the predicate device.