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

Apex Dental Materials, Inc.
Scott Lamerand
Owner
330 Telser Road
Lake Zurich, Illinois 60047

March 17, 2017

Re: K161077
Trade/Device Name: RnD TE and RnD SE
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: February 15, 2017
Received: February 17, 2017

Dear Scott Lamerand:

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,

Susan Runner DDS, MA

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)*
K161077

Device Name

RnD TE and RnD SE

Indications for Use *(Describe)*

RnD TE and RnD SE is indicated for
- Desensitizing
- Rewetting
- Preventing Bond Degradation

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K161077
510(k) Summary

1) Submitter Information:

Apex Dental Materials, Inc
330 Telser Road
Lake Zurich, IL 60047
Registration Number: 3004402215

2) Contact Information:

Scott Lamerand Owner
Telephone (Office): 847-719-1133
Telephone (Mobile): 847-975-0425
Fax: 847-719-1122
Email: Scott.Lamerand@apexdentalmaterials.com

3) Date Submitted: March 17, 2017

4) Device Name:

Trade Name: RnD TE and RnD SE
Common Name: Tooth Conditioner

Classification Name: Resin Tooth Bonding Agent
Regulation: 872.3200
Device Class: Class II
Product Code: KLE

5) Predicate Devices:

Predicate Device	510K Number	Company Name	Commercial Name
HEMA-GLU	K951220	Health-Dent'l, LLC	HEMA-GLU
Wet Prep	K961822	Bisco, Inc	Aqua Prep F Rewetting and Desensitizer
Hemaseal & Cide	K990779	Advantage Dental Products	Hemaseal &Cide Desensitizer

6) Description of Subject Device:

RnD TE and RnD SE is an aqueous primer used to rewet and desensitize a tooth prior to bonding. Bonding to tooth structure presents many challenges including the determination of the proper conditions for starting the bonding protocol. The tooth can be left too wet or too dry which could lead to debonding or post-operative sensitivity. RnD TE and R&D SE have been designed to aid in reaching the appropriate moisture level to provide an initial surface that allows an adhesive to reach its full potential.

The subject device formulations also work to ensure the long term bond integrity by limiting the development of matrix metalloproteinases (MMP's) that have been cited as a contributor to bond degradation over time.

RnD TE and RnD SE will be sold as a kit contain a 3ml bottle of RnD along with a single cavity well and Mircobrush® applicators. RnD has been designed as a single use material and is non-sterile. The material is a single component material that is applied directly to the tooth with no other components added prior to use.

7) Indications for Use:

1) Rewetting tooth surface prior to bonding
2) Desensitizing
3) Preventing bond degradation

The indications for use for the proposed device are smiliar to the indications for use for the predicate devices: HEMA-GLU (K951220) and Hemaseal & Cide (K990779). Aqua Prep F (K961822) does not specifically address any impacts on bond degradation but is consistent in stressing rewetting and desensitizing. The indications for use are similar for two of the three predicate devices, and thus the materials are substantially equivalent in terms of intended use.

A comparison table of the indications for use is shown below:

Device	**Subject Device K161077 RnD TE and RnD SE**	**Primary Predicate K951220 HEMA GLU**	**Reference K961822 Aqua Prep**	**Reference K990779 Hemaseal & Cide Desenstizer**
Indications for Use Statement	1) Rewetting tooth surface prior to bonding 2) Desensitizing 3) Preventing bond degradation	1) uperior desensitizing agent, to be placed under dental cements or other restorative materials – temporary, provisional or final. 2) can be used for desensitization of amalgam restorations, either conventional or bonded. 3) helps kill bacteria, 4) alter nerve responses 5) aids bonding primers in penetrating etched dentin.	1) Rewetting dentin and enamel following etching and drying of the dental cavity preparation 2) Rewetting dried hydrophilic dental tissues following dental procedures 3) Rewetting etched and dried enamel prior to Pit & Fissure Sealant treatment 4) Desensitizing	1) Elimination of post-op sensitivity - precluding the need to do remakes 2) Superior disinfection of preparations 3) Enhancement and prolongation of bond strength 4) Reduction of microleakage

8) Technological Characteristics:

All components of RnD formulations are found in legally marketed predicate devices and are industry standard materials used in rewetting and desensitizing materials for more than 20 years. The final characteristics and indications for use are similar to other legally marketed devices with similar indications for use. The proposed device utilizes a solvent coupled with glutaraldehyde, methacrylate monomer and sodium fluoride to provide the stated benefits.

9) Predicate Device Comparison

All of the components utilized within the RnD formulations are industry standard materials used in similar materials which have the same indications for use. The following table further substantiates this claim:

Property	**Subject Device K161077**		**Primary Predicate K951220**	**Reference K961822**	**Reference K990779**
Device 510K Name	RnD TE	RnD SE	HEMA GLU	Aqua Prep F	Hemaseal & Cide Desenstizer
Commercial Name	RnD TE	RnD SE	HEMA GLU	Aqua Prep F	Hemaseal & Cide Desenstizer
510K Number	K161077	K161077	K951220	K961822	K990779
Manufacturer	Apex Dental Materials, Inc.	Apex Dental Materials, Inc.	Health-Dent'l LLC	Bisco, Inc	Advantage Dental Products
Classification	KLE	KLE	KLE	KLE	LBH

Indications for Use: **Desensitizing**	Yes	Yes	Yes	Yes	Yes
Indications for Use: **Rewetting**	Yes	Yes	Yes	Yes	Yes
Indications for Use: **Improve Bond Strength**	Yes	Yes	Yes	Yes	Yes
Bond Strengths to Dentin (*) Mean (sd), [n]	36.2 (5.7) [5]	33.4 (4.7) [5]	31.7 (2.0) [5]	29.1 (3.1) [5]	36.9 (3.1) [5]
Bond Strengths to Enamel (*) Mean (sd), [n]	32.1 (2.9) [5]	27.8 (3.9) [5]	32.3 (2.8) [5]	27.2 (3.5) [5]	37.1 (3.0) [5]
Film Thickness	4 microns	4 microns	5 microns	4 microns	5 microns
pH	Neutral	Neutral	Neutral	Neutral	Neutral
Components	Aqueous primer containing desensitizing components, specifically Glutaraldehyde, NaF and HEMA	Aqueous primer containing desensitizing components, specifically Glutaraldehyde, NaF and HEMA	Aqueous primer containing desensitizing components, specifically Glutaraldehyde and HEMA	Aqueous primer containing desensitizing components, specifically HEMA and NaF	Aqueous primer containing desensitizing components, specifically HEMA and Chlorhexidine Gluconate
Application: Surface to be applied to	Dentin	Dentin	Dentin	Dentin	Dentin

Application: **# of coats (Amount)**	1 coat	1 coat	1 coat	1 coat	1 coat
Application: **Dwell Time on Tooth Surface**	5 seconds	5 seconds	15 – 30 seconds	20 seconds	10 – 15 seconds
Application: **Dried or Left Moist**	Left moist	Left moist	Left moist	Left moist	Left moist

(*) Shear bond testing was completed utilizing the Notched Edge Shear Bond Strength test method.

10) <u>Discussion of Substantial Equivalence:</u>

The subject device has the same intended use and technical characteristics as the named predicate devices. The indications for use for the proposed device are similar to the indications for use for the predicate devices: HEMA-GLU (K951220) and Hemaseal & Cide (K990779). Aqua Prep F (K961822) does not specifically mention any impacts on bond degradation in its indications for use, but is consistent with the subject device in including rewetting and desensitizing. The final predicate device which does not contemplate bond degradation is still used in a consistent manner with similar uses. All of the components utilized within the RnD formulations are industry standard materials used in similar materials which have the same indications for use.

Differences are also noted between the subject and predicate devices. The subject device demonstrates higher bond strength to dentin than its primary predicate, and a slightly decreased film thickness. While the material composition of the subject device features all components observed in the primary predicate, the subject device also featured NaF as part of its formulation, unlike the primary predicate. Reference devices are included to address these differences noted between the subject and primary predicate devices.

The specifications that are important to determine substantial equivalency of a dental adhesive system are bond strengths associated to enamel and dentin (tooth structure). The bond strengths as noted in above table compare the primary predicate device HEMA GLU (K951220) to the subject device. In both enamel and dentin bonding, the results were equivalent.

11) <u>Clinical and Non-clinical Performance Data:</u>

No clinical testing was required to support the applicant device as the indications for use and components are equivalent to the predicate devices along with other legally marketed products.

These types of products have been utilized within the Dental Industry for more than 20 years with no reported adverse effects. The non-clinical testing of the proposed device included ISO 29022:2013 – Dentistry – notched edge shear bond strength test. The method includes substrate selection, storage and handling of tooth structure, as well as the procedure for testing.
Nonclinical test data supports the stated equivalence of the subject and predicate devices.

12) Conclusion:

The subject device has the same intended use and technical characteristics as the named predicate devices. Device comparisons presented above illustrates this with a direct comparison of the devices in terms of intended use, components, and function. As such, the subject device may be considered substantially equivalent to the predicate devices.