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

November 20, 2015

E Dental Products
Jeff Banyas, DDS
Owner
216 W. Watauga Ave.
Johnson City, Tennessee 37604

Re: K152110
Trade/Device Name: E Dental Products e-1 Etchants
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: August 15, 2015
Received: August 25, 2015

Dear Dr. Banyas:

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,

for Erin I. Keith, M.S.
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)*
K152110

Device Name
E Dental Products e-1 etchants

Indications for Use *(Describe)*

Etch enamel, dentin, and glass ionomer cements

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:

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Food and Drug Administration
Office of Chief Information Officer
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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."

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216 West Watauga Ave.
Johnson City, TN 37604

eDentalProducts.com

E Dental Products
1-844-289-3824

510(k) Summary

November 17, 2015

7a. 510(k) Submitter/Contact:

Owner: E Dental Products
216 W. Watauga Ave.
Johnson City, TN 37604 USA
423-426-3221
fax 423-928-0266 (M-F 8-5 only)

Contact: Dr. Jeff Banyas
216 W. Watauga Ave
Johnson City, TN 37604 USA
423-426-3221
fax 423-928-0266 (M-F 8-5 only)

7b. Name of device:

Trade name – E Dental Products e-1 etchants
510(k) number – K152110
Classification name – Resin tooth bonding agent
21 CFR 872.3200
Product code KLE
Common Name – phosphoric acid gel etch

7c. Predicate Device:

Trade name - Pulpdent Etch-Royale
510(k) Number - K031915
Classification: Resin tooth bonding agent
Product code: KLE
21 CFR 872.3200
Common name – phosphoric acid gel etch

7d. Description:

E Dental Products e-1 etchants are colored 37% phosphoric acid aqueous solution etching gels. e-1 etchants are applied to the tooth surface with an applicator tip and they are easily rinsed off with water. They are used by dental professionals as one step in the tooth restoration process.

7e. Indications for Use:

Etch enamel, dentin, and glass ionomer cements.

7f. Comparison with predicate:

E Dental Products e-1 etchants are substantially equivalent in design, composition, performance, and intended use to the predicate device that has been give 510(k) clearance as a Class II Dental Device under CFR 872.3200.

	E Dental Products e-1 etchants K152110	**Pulpdent Etch Royale K031915**
Chemical composition	37% phosphoric acid silica colorant	37% phosphoric acid silica glycerin colorant
Consistency	soft gel	soft gel
Color	colored	dark blue
Intended use	Etch enamel, dentin and glass ionomer cements.	Etch enamel, dentin and glass ionomer cements.

7g. Substantial Equivalence Discussion:

Intended uses

The intended uses of the subject devices and predicate are identical. Accordingly, the intended uses of the subject devices are substantially equivalent to that of the predicate device.

Chemical Ingredients

E Dental Products e-1 etchants and the predicate device contain the same concentrations of phosphoric acid and both contain silica and colorant. All ingredients in the subject devices are substantially equivalent to the predicate device. Regarding the predicate device, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US. In conclusion, it can be said that the subject device is substantially equivalent to that of the predicate device.

Technological Characteristics

There is no difference between indications for use between the subject devices and the predicate device. There is no difference between the subject devices and the predicate device in regards to technology; as the active ingredient, phosphoric acid, is the same in both the subject devices and the predicate device.

E Dental Products e-1 etchants and the predicate device are both filled in syringes. Both subject devices and predicate device are applied directly to the tooth through a dispensing tip.

7h. Summary of Performance Testing - Bench

It was confirmed that the pH value, solubility in water, specific gravity, appearance, shelf life and odor of the subject devices were equivalent to the predicate device.

The following test results demonstrate that E Dental Products e-1 etchants perform as intended. Accordingly, it was concluded that the performance and shelf life of the subject devices were substantially equivalent to those of the predicate device.

	E Dental Products e-1 etchants K152110	Pulpdent Etch-Royale K031915
Specific gravity @ 25C	1.31	1.30
Solubility in water @25C	100%	100%
pH @25C	1	1
appearance	colored soft gels	dark blue soft gel
shelf life	2 years	2 years
odor	mild characteristic	mild characteristic

7i. Biocompatibility:

The subject devices are categorized into an external communicating device that may contact dentin and whose duration is less than 24 hours. Actual contact with the dentin is 15 seconds and 30 seconds with enamel and glass ionomer cements.
Biocompatibility testing was not conducted because of the similarity in composition between the predicate device and the subject devices and no new chemical components have been added.
The subject devices and predicate device are substantially equivalent in all relevant aspects, are composed of equivalent materials, and have equivalent manufacturing methods.
Regarding the predicate device, there have not been any reported problems or recalls according to the post market adverse event reporting requirements in the US.
Accordingly, it was determined that the subject devices were substantially equivalent to the predicate device.

7j. Conclusion:

Based on technological characteristics, non-clinical performance data, and side by side comparisons of the subject devices to the predicate device, it can be concluded that E Dental Products e-1 etchants are substantially equivalent in design, composition, performance, and intended use to the predicate device that has been given 510(k) clearance as Class II dental device under CFR 872.3200.