January 28, 2022

Rounding Third LLC
Adrienne Foller
Regulatory Consultant
QRS Solutions LLC
966 E. 2050 N
North Ogden, Utah 84414

Re: K213093
Trade/Device Name: STEP-1 PumEtch
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE, EJR
Dated: November 29, 2021
Received: December 1, 2021

Dear Adrienne Foller:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213093

Device Name
STEP-1 PumEtch

Indications for Use *(Describe)*

STEP-I PumEtch is a prophylaxis and phosphoric acid etchant treatment intended for the srnface preparation of dentin or enamel prior to tooth restoration, including the application of sealants or for bonding.

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.

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Section 5
K213093
510(k) Summary

Name of Sponsor:	Smile Stream, LLC 9750 East Easter Avenue, #155 Centennial, CO 80112
510(k) Contact:	Adrienne von Foller Regulatory Affairs Consultant QRS Solutions, LLC Telephone: (801) 916-8188 AVonFoller@qrssolutionsllc.com
Date Prepared:	29 November 2021
Submission Type:	Traditional 510(k)
Proprietary Name:	STEP-1 PumEtch
Common Name:	Resin tooth bonding agent
Classification:	21 CFR 872.3200
Device Class:	Class II
Device Product Code:	KLE, EJR
Predicate Device:	Premier Etch
510(k) Applicant:	Premier Dental Company Products
510(k):	K141839
Primary Reference Device:	Enamel Pro
510(k) Applicant:	Premier Dental Company Products
510(k):	K062166
Secondary Reference Device:	DiaEtch
510(k) Applicant:	DiaDent Group International
510(k):	K192273

5.1 Device Description

STEP-1 PumEtch is a tooth preparation formulation combining a 37% phosphoric acid etch and pumice, a polishing agent, into one gel liquid solution. The product is used to prepare natural tooth surfaces for the application of sealants or direct bond appliances.

5.2 Indications for Use

STEP-1 PumEtch is a prophylaxis and phosphoric acid etchant treatment intended for the surface preparation of dentin or enamel prior to tooth restoration, including the application of sealants or for bonding.

5.3 Basis for Substantial Equivalence:

STEP-1 PumEtch has the same technological characteristics as the predicate device, including:

1. Indications for use
2. Intended use
3. Basic principles of operation
4. Basic formula

The following comparative performance testing was conducted which demonstrated there is no statistically significant difference between the subject and predicate devices.

- Shear Bond Strength (SBS)
- pH

The fundamental scientific technology of STEP-1 PumEtch is the same as the previously cleared predicate device. No animal or clinical studies were deemed necessary for a determination of substantial equivalence.

The intended use of the subject device is the same as the predicate device. Based on similarities in indications for use, basic design, and the principle of operation, the STEP-1 PumEtch is substantially equivalent to the previously cleared predicate device.

A primary reference device has been included to support the safety and common use of pumice as a dental prophylaxis. A secondary reference device has been included to support the safety and common use of xanthan gum as a thickening agent in a dental etchant. However, substantial equivalence of the subject device to the reference devices is not required.