September 2, 2020

Daisy Ni, Regulatory Affairs Manager
Belport Company, Inc., Gingi-Pak
4825 Calle Alto,
Camarillo, California 93012

Re: K200462
Trade/Device Name: EtchPro Etching Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: June 1, 2020
Received: June 5, 2020

Dear Daisy Ni:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number : K200462

Device Name: EtchPro® Etching Gel

Indications for Use:

EtchPro® Etching Gel is intended to be used by dental professionals to etch the dentin and enamel before tooth restoration treatments.

Type of Use:

Prescription Use ___X___ OR Over-The-Counter Use

K200462
510(k) Summary

Date Prepared:

September 1, 2020

Applicant:

Belport Company, Inc., Gingi-Pak

Address: 4825 Calle Alto, Camarillo, CA 93012

Telephone: (805) 484-1051

Correspondent Contact:

Daisy Ni, Regulatory Affairs Specialist

- Telephone: (805) 484-1051
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Jiahe Li, Regulatory Affairs Specialist

- Telephone: (805) 484-1051

Device Information:

DEVICE NAME: EtchPro® Etching Gel

TRADE NAME: EtchPro® Etching Gel

COMMON NAME: Tooth etching gel

DEVICE CLASSIFICATION Name: Resin, Tooth Bonding Agent

CLASSIFICATION REGULATION NUMBER: CFR 872.3200
DEVICE CLASSIFICATION: CLASS II
CLASSIFICATION PRODUCT CODE: KLE

Predicate Device

	Product Name	Registration No.	Manufacturer
Predicate Device	Etch-Rite Royale	K031915	Pulpdent Corporation
Reference Device	Acid Etch Gel	K882576	Pulpdent Corporation

Description of Device

EtchPro® Etching Gel is a 38% phosphoric acid etching gel in a soft gel form that is used by dental professionals for etching dentin and enamel before tooth restoration.

Indications for Use

EtchPro® Etching Gel is intended to be used by dental professionals to etch the dentin and enamel before tooth restoration treatments.

Substantial equivalence

A side-by-side comparison table is provided. The similarities among the subject, predicate and reference devices are discussed below.

Item Name	**Subject device**	**Predicate Device**	**Reference Device**	**Substantial equivalence Analysis**
Device name	EtchPro® Etching Gel	Etch- Rite Royale	Acid Etch Gel (Etch-Rite)	-
Manu-facturer	Belport Company, Inc., Gingi-Pak	Pulpdent Corporation	Pulpdent Corporation	-
510(K) No.	K200462	K031915	K882576	-
Classifi-cation Name	Resin, Tooth Bonding Agent	Resin, Tooth Bonding Agent	Tooth shade resin material.	Same as the predicate device
Regula-tory Class	Class II	Class II	Class II	Same
Product Code	KLE	KLE	EBF	Same as the predicate device
Intended Use	Etch the dentin or enamel	Etching dentin or enamel	Etch the dentin, enamel and glass ionomer cements	Same as the predicate device
Descrip-tion of Device	EtchPro® Etching Gel is a 38% phosphoric acid etching gel in a soft gel form that is used by dental professionals for etching dentin and	Pulpdent Etch-Rite Royale is a 37% phosphoric acid etchant in gel form that is used by the dental professional for etching dentin or enamel	Etch-Rite Etching Gel is a 38% phosphoric acid etching gel in a thixotropic gel form that is used by the dental professional for etching dentin or enamel before tooth restoration.	Same as the reference device for active ingredient and concentration. Same as the predicate for the soft gel form.

	enamel before tooth restoration.	before tooth restoration. Etch-Rite Royale is dark blue for contrast with tooth enamel and easy visualization. Etch-Rite Royale is a soft gel that is easily manipulated and that rinses completely without leaving any residue		All devices are for dental professional use.
Ingre-dient	38% phosphoric acid Silica Glycerin Colorant	37% phosphoric acid Silica Glycerin Colorant	38% phosphoric acid Silica Colorant	Same ingredients Same as the reference device for the concentration of active ingredient (38% phosphoric acid).
Consis-tency	Soft gel	Soft gel	Thixotropic gel	Same as the predicate device
Color	Dark blue	Dark blue	Medium blue	Same as the predicate device
Solubility in water	100%	100%	100%	Same
Design/ Packagin g	Pre-filled syringes with applicators, in 1.2 ml and 30 ml	Pre-filled syringes with applicators, in 1.2 ml, 6ml and 25 ml	Pre-filled syringes with applicators, in 1.2 ml and 25 ml	Same packing/design except volume differences.
OTC or Rx	Rx	Rx	Rx	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Shelf Life	2 years	2 years	2 years	Same

The intended use of the EtchPro® Etching Gel is same to that of the predicate device Pulpdent Etch-Rite Etching Gel as they are both indicated to Etch dentin and enamel. EtchPro® Etching, predicate device and reference device share the same ingredients, except EtchPro® Etching

Gel includes glycerin while Acid Etch Gel (Etch-Rite) does not. Glycerin is a humectant, a FDA recognized generally recognized as safe (GRAS) inactive ingredient.

Non-Clinical performance Data

The side-by-side performance tests with EtchPro® Etching Gel and Acid Etch Gel (Etch-Rite) were conducted. The following items were tested: phosphoric acid concentration, pH, and viscosity. The biocompatibility tests were performed and the data showed that EtchPro® Etching Gel is substantial equivalent to Acid Etch Gel (Etch-Rite).

Clinical performance Data

Clinical data was not included in this submission.

Conclusion

Based on the similarities in indications for use and technological characteristics together with results of non-clinical performance testing, we believe that EtchPro® Etching Gel is substantially equivalent to the predicate devices.