October 27, 2026

The Belport Company Inc., DBA Gingi-Pak
Nikki Huynh
Regulatory Affairs Specialist
4825 Calle Alto
Camarillo, California 93012

Re: K262775
Trade/Device Name: AquaVance Clear Fluoride Treatment
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: Class II
Product Code: LBH
Dated: August 4, 2026
Received: August 5, 2026

Dear Nikki Huynh:

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 (the 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 available 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.

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

BOBAK SHIRMOHAMMADI -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262775

Please provide the device trade name(s).

AquaVance Clear Fluoride Treatment

Please provide your Indications for Use below.

Indicated for the treatment of hypersensitive teeth.

Please select the types of uses.	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K262775

510(k) Summary

Prepared on: 2026-08-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	The Belport Company Inc. DBA Gingi-Pak
Applicant Address	4825 Calle Alto Camarillo CA 93012 United States
Applicant Contact Telephone	(909) 839-0888
Applicant Contact	Mr. Daniel Gallegos
Applicant Contact Email	aaron.gallegos@pac-dent.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	AquaVance Clear Fluoride Treatment
Common Name	Cavity varnish
Classification Name	Varnish, Cavity
Regulation Number	872.3260
Product Code(s)	LBH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231338	3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment	LBH

Device Description Summary

21 CFR 807.92(a)(4)

AquaVance Clear Fluoride Treatment is an aqueous fluoride coating that is applied topically to tooth surfaces by a dental professional for the treatment of hypersensitive teeth. The product contains 2.1% w/w sodium fluoride, providing approximately 9,500 ppm fluoride ion (equivalent to approximately 0.95% fluoride ion). The formulation is designed to form a thin film on the tooth surface after application. Following application, the aqueous solvent system evaporates, allowing the film-forming polymer to form a thin adherent coating on the tooth surface that retains sodium fluoride at the treatment site.

AquaVance Clear Fluoride Treatment contains a film-forming polymer system, fluoride source, sweeteners, flavoring agents, surfactant, preservative, and aqueous solvent system. The product is intended for professional dental use and is supplied in unit-dose packaging. Each package contains 0.50 mL of the coating and may be offered in Mint, Strawberry, or Flavorless versions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Indicated for the treatment of hypersensitive teeth.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device and predicate device have identical indications for use: Indicated for the treatment of hypersensitive teeth.

Technological Comparison

21 CFR 807.92(a)(6)

AquaVance Clear Fluoride Treatment has the same intended use and fundamental technological characteristics as the predicate device,

3M™ Clinpro™ Clear 2.1% Sodium Fluoride Treatment (K231338). Both devices are Class II cavity varnish products indicated for the treatment of hypersensitive teeth and function through the same principle of operation by occluding dentin tubules to reduce dentin permeability and sensitivity.

The subject and predicate devices share the same active ingredient concentration, route of administration, dosage form, prescription status, biocompatibility profile, and non-sterile presentation. Although there are formulation differences between the devices, these differences do not raise new questions of safety or effectiveness because the devices maintain the same intended use, mechanism of action, user population, exposure conditions, and performance expectations.

Performance testing conducted in accordance with recognized standards demonstrated comparable characteristics between the subject and predicate devices, including visual appearance, viscosity, pH, fluoride release, and dentin permeability reduction. These data support that AquaVance Clear Fluoride Treatment performs as intended and is technologically comparable to the predicate device. Therefore, the subject device is substantially equivalent to the identified predicate with respect to design, materials, principle of operation, performance characteristics, and intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Summary of Non-Clinical Testing

Performance testing was conducted to evaluate the performance characteristics of AquaVance Clear Fluoride Treatment and compare them to the predicate device, 2.1% Sodium Fluoride Treatment (K231338). Testing was performed in accordance with ISO 17730.

The following bench performance characteristics were evaluated:

Visual appearance
Viscosity
pH
Fluoride release
Dentin permeability reduction

Results demonstrated that AquaVance Clear Fluoride Treatment exhibited performance comparable to the predicate device, including:

Homogeneous, clear to slightly opalescent appearance.
Viscosity of 128 cP compared to 121 cP for the predicate device.
pH of 6.4 compared to 6.3 for the predicate device.
Fluoride release of 19.1 ± 0.10 ng F/mm^2 at 24 hours compared to 18.3 ± 0.10 ng F/mm^2 for the predicate device.
Dentin permeability ratio of 99.18%, comparable to 99.19% for the predicate device.

Additional cumulative fluoride release testing demonstrated that AquaVance Clear Fluoride Treatment met the acceptance criterion of ≥14.2 ng F/mm^2 at 24 hours, achieving 19.1 ng F/mm^2. The fluoride release profile was comparable to the predicate device, which achieved 18.3 ng F/mm^2 at 24 hours.

Conclusions

The bench testing results demonstrate that AquaVance Clear Fluoride Treatment meets established performance specifications and performs comparably to the predicate device with respect to physical characteristics, fluoride release, and dentin permeability reduction. All acceptance criteria were met, and the testing supports the conclusion that AquaVance Clear Fluoride Treatment is substantially equivalent to the predicate device and is suitable for its intended use in the treatment of hypersensitive teeth.

Clinical Testing: No clinical testing was required or performed to support this submission.