August 7, 2026

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

Re: K261937
Trade/Device Name: PacTemp Automix NE
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: June 9, 2026
Received: June 10, 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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 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,

FDA 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.	K261937

Please provide the device trade name(s).

PacTemp Automix NE

Please provide your Indications for Use below.

PacTemp Automix NE is indicated for temporization of provisional prostheses or restorative procedures, including provisional crowns, bridges, inlays, and onlays.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter: The Belport Company, Inc., dba Gingi-Pak
Address: 4825 Calle Alto, Camarillo, CA 93012
Contact Person: Nikki Huynh
Title: Regulatory Specialist
Phone: (805) 484-1051
Email: nikki.huynh@gingi-pak.com
Date Prepared: 06/08/2026

Trade Name: PacTemp Automix NE
Common Name: Temporary Dental Cement
Submission Type: Traditional 510(k)
Submission Number: K261937
Regulation Name: Dental Cement
Regulation Number: 21 CFR 872.3275
Product Code: EMA
Device Class: Class II

Device Description

PacTemp Automix NE is a non-eugenol temporary resin dental cement intended for professional dental use in provisional cementation procedures. The device is supplied as a two-component automix system consisting of base and catalyst pastes delivered through a dual-barrel syringe with disposable mixing tips. Upon mixing, the material undergoes a chemically activated curing reaction to form a temporary resin cement.

Indications for Use

PacTemp Automix NE is indicated for temporization of provisional prostheses or restorative procedures, including provisional crowns, bridges, inlays, and onlays.

Predicate Device

The following legally marketed device was used as the predicate device:
510(k) Number: K211237

510(k) Trade Name: UltraTemp Rez II

Manufacturer: Ultradent Products, Inc.

Address: 505 W 10200 S, South Jordan, UT 84095

Regulation Number & Code: 21 CFR 872.3275; EMA

Regulation Name: Dental Cement

Regulatory Class: Class II

Clearance Date: July 13, 2021

Technological Characteristics

PacTemp Automix NE is a resin-based, non-eugenol temporary dental cement utilizing methacrylate resin chemistry and a chemically activated curing mechanism. The device is supplied in an automix dual-barrel syringe delivery format and is intended for professional dental use.

A comparison of the technological characteristics of the subject device and predicate device is provided below:

Parameter	**Subject Device PacTemp Automix NE**	**Predicate Device UltraTemp Rez II** (K211237)	**Substantial Equivalence with Predicate Device**
Manufacturer	The Belport Company, Inc., dba Gingi-Pak	Ultradent Products, Inc.	
Product Type	Non-eugenol temporary dental cement	Non-eugenol temporary dental cement	Substantially equivalent
Regulatory Class	Class II	Class II	Substantially equivalent
Sterility	Non-sterile	Non-sterile	Substantially equivalent
Intended User	Professional dental use	Professional dental use	Substantially equivalent
Indications for Use	For temporization of provisional prostheses or restorative procedures (i.e. provisional crowns, bridges, inlays, and onlays)	For temporization of provisional prostheses or restorative procedures (i.e. provisional crowns, bridges, inlays, and onlays)	Same intended use
Principle of Operation	Two-component temporary cement that sets after mixing to form a temporary luting material	Two-component temporary cement that sets after mixing to form a temporary luting material	Substantially equivalent

Parameter	Subject Device PacTemp Automix NE	Predicate Device UltraTemp Rez II (K211237)	Substantial Equivalence with Predicate Device
Curing / Setting Mechanism	Chemical cure / self-cure after mixing of base and catalyst	Chemical cure / self-cure after mixing of base and catalyst	Substantially equivalent
Delivery Format	Automix dual-barrel syringe with disposable mixing tips	Automix dual-barrel syringe with disposable mixing tips	Substantially equivalent
Design	Two-component base/catalyst system	Two-component base/catalyst system	Substantially equivalent
Material Type	Resin-based temporary dental cement	Resin-based temporary dental cement	Substantially equivalent
Eugenol Content	Non-eugenol	Non-eugenol	Substantially equivalent
Handling Characteristics	Easy handling, mixing, seating, temporary retention, and removability.	Easy handling, mixing, seating, temporary retention, and removability.	Substantially equivalent
Composition			
Chemical Composition	Resin-based temporary dental cement containing methacrylate monomers, fillers, initiators, stabilizers, and pigments.	Resin-based temporary dental cement containing methacrylate monomers, fillers, initiators, stabilizers, and pigments.	Both devices utilize methacrylate resin chemistry and the same fundamental scientific technology.
Non-Clinical Performance Test Data			
Performance Standard	ISO 9917-2 and recognized dental cement test methods	ISO 9917-2 and recognized dental cement test methods	Substantially equivalent
Shear bond strength (MPa)	14.8	13.6	Substantially equivalent
Flexural Strength (MPa)	27.4	21.2	Substantially equivalent
Water Solubility ($\mu g/mm^3$)	0.4	0.8	Substantially equivalent
Water Sorption ($\mu g/mm^3$)	32	28	Substantially equivalent
Working Time (seconds)	90-120	100-150	Substantially equivalent
Setting Time (minutes)	< 4	< 5	Substantially equivalent
Radiopacity (% Aluminum)	190	180	Substantially equivalent
Film Thickness (µm)	22.5	20	Substantially equivalent

Performance Data

Bench testing was conducted to evaluate physical and functional performance characteristics relevant to the intended use of the device. Testing included:

- Shear bond strength
- Flexural strength
- Water solubility
- Water sorption
- Working time
- Setting time
- Radiopacity
- Film thickness

Testing was conducted using ISO 9917-2:2017 and recognized dental cement test methods, as appropriate.

Biocompatibility

A biocompatibility assessment was conducted in accordance with FDA Guidance Use of ISO 10993-1. The evaluation considered the nature and duration of device contact, material composition, predicate comparison, and risk management information. PacTemp Automix NE was determined to be biocompatible for its intended use and does not raise new questions of biological safety.

Conclusions

PacTemp Automix NE has the same intended use as the predicate device, UltraTemp Rez II (K211237). Both devices are non-eugenol temporary resin dental cements intended for provisional cementation procedures and utilize the same fundamental scientific technology. Bench testing demonstrated comparable performance characteristics. The information provided supports a determination that PacTemp Automix NE is substantially equivalent to the predicate device.