



September 24, 2026

Den-Mat Holdings, LLC
Brianna Alvarez
Regulatory Affairs Specialist
1017 W. Central Ave.
Lompoc, California 93436

Re: K262252

Trade/Device Name: MPa Max adhesive
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: July 1, 2026
Received: July 2, 2026

Dear Brianna Alvarez:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, 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.

K262252

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Please provide the device trade name(s).

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MPa Max adhesive

Please provide your Indications for Use below.

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Use for virtually all bonding needs in restorative dentistry for dental patients of all ages. MPa Max adhesive bonds to the following materials:

- Dentin and enamel
- Porcelain (hydrofluoric acid and silane required)
- Zirconia
- Metal
- Composite

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](#))

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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)

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K262252 - 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information	21 CFR 807.92(a)(1)
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Submitter: Den-Mat Holdings, LLC
1017 W. Central Avenue
Lompoc, CA 93436 USA
Phone: 805-346-3700
Establishment Registration Number: 2018957

Contact Person: Brianna Alvarez
Regulatory Affairs Specialist
Phone: 805-346-3700
Email: regulatory@denmat.com

Date Prepared: September 8, 2026

Device Information	21 CFR 807.92(a)(2)
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Trade Name: MPa™ Max adhesive
Common Name: Dental tooth bonding resin
Regulation Number: 21 CFR 872.3200
Regulation Name: Agent, Tooth Bonding, Resin
Classification: Class II
Product Code: KLE
Review Panel: Dental

Legally Marketed Predicate Devices	21 CFR 807.92(a)(3)
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Device Trade Name: Peak™ Universal Bond
510(k) Number: K100752 (Primary Predicate)
Product Code: KLE

Device Trade Name: Peak™ Universal Bond
510(k) Number: K240743 (Secondary Predicate)
Product Code: KLE

Device Description	21 CFR 807.92(a)(4)
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MPa Max adhesive is a bottle delivered bonding resin. It can be used with total-etch techniques. It is 7.5% filled with an ethyl alcohol solvent carrier and will cure with most high intensity lights including LEDs. MPa Max adhesive contains 0.2% chlorhexidine which may ensure long term bond strengths. The resin is intended for bonding restorative materials to dentin, enamel, porcelain, zirconia, metal, and composite.

MPa Max is used with an etch-and-rinse bonding technique. Dentin and enamel are etched with phosphoric acid, rinsed with water, and prepared in accordance with the instructions for use before application of the adhesive. Phosphoric-acid etching removes or modifies the smear layer and demineralizes the superficial tooth structure to facilitate penetration of the adhesive into the prepared substrate.

The ethanol-based formulation facilitates penetration of the adhesive resin into the prepared dentin surface. Upon light curing, the adhesive forms a polymerized bonding layer between the prepared tooth structure and restorative material through chemical bonding and micromechanical interlocking.

MPa Max has a viscosity designed to facilitate application and coating of the prepared bonding surfaces. The cured adhesive has a film thickness of approximately 2 µm.

Intended Use / Indications for Use	21 CFR 807.92(a)(5)
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Use for virtually all bonding needs in restorative dentistry for dental patients of all ages.

MPa Max adhesive bonds to the following materials:

- Dentin and enamel
- Porcelain (hydrofluoric acid and silane required)
- Zirconia
- Metal
- Composite

Comparison of Technological Characteristics	21 CFR 807.92(a)(6)
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MPa Max adhesive is substantially equivalent to the predicate devices Peak Universal Bond in terms of design, chemical composition, mode of action, principle of operation, manufacturing, packaging, and labeling. While the indications for use for the subject and primary predicate devices are substantially equivalent, the subject device can also bond to Zirconia. The secondary predicate device is included specifically to support this additional material compatibility. Any differences between the subject and predicate devices are considered minor and do not raise new questions concerning safety and effectiveness.



	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comparison
Device Name	MPa Max Adhesive	Peak Universal Bond	Peak Universal Bond	N/A
Manufacturer	Den-Mat Holdings, LLC	Ultradent Products, Inc.	Ultradent Products, Inc.	N/A
510(k) number	K262252	K100752	K240743	N/A
Classification Name	Agent, Tooth Bonding, Resin	Agent, Tooth Bonding, Resin	Agent, Tooth Bonding, Resin	Identical
Regulation Number	21 CFR 872.3200	21 CFR 872.3200	21 CFR 872.3200	Identical
Product Code	KLE	KLE	KLE	Identical
Indications for Use	Use for virtually all bonding needs in restorative dentistry for dental patients of all ages. MPa Max adhesive bonds to the following materials: • Dentin and enamel • Porcelain (hydrofluoric acid and silane required) • Zirconia • Metal • Composite	Use for virtually all etching and bonding needs in restorative dentistry for dental patients of all ages. Peak Universal Bond bonds to the following materials: • Dentin and enamel • Porcelain • Metal • Composite	Use for virtually all etching and bonding needs in restorative dentistry for patients of all ages. Peak Universal Bond is used for desensitizing/sealing of tooth structure. Peak Universal Bond adhesive bonds to the following materials: • Dentin and Enamel • Porcelain, Zirconia • Metal • Composite	While the indications for use for the subject and primary predicate devices are substantially equivalent, the subject device can also bond to zirconia. The secondary predicate device is included specifically to support this additional material compatibility.
Delivery System	Bottle	Bottle	Bottle	Identical
Sterile	No	No	No	Identical
Curing Mechanism	Light-cure	Light-cure	Light-cure	Identical

Performance Data

21 CFR 807.92(b)

21 CFR 807.92(b)(1) – Non-Clinical Testing

Non-clinical performance testing was conducted on representative samples of MPa Max adhesive to evaluate shear bond strength and the light-protection performance of the primary packaging.

Shear Bond Strength

Shear bond strength testing was conducted in accordance with ISO 29022:2013, Dentistry — Adhesion — Notched-edge shear bond strength test. Seven samples per substrate were evaluated for dentin, enamel, porcelain, metal, composite, and zirconia. All samples met the predefined acceptance criterion of a minimum shear bond strength of 25 MPa.

Light-Protection Performance of Primary Packaging

An in-house test method was used to evaluate the ability of the primary packaging bottle to protect MPa Max adhesive from light exposure. Two bottles containing MPa Max adhesive were tested. Each bottle was first exposed to a high-intensity light source for 5 minutes, after which adhesive was expressed from the bottle and evaluated for its ability to cure. The same bottles were then exposed to a standard light source for an additional 10 minutes, after which the adhesive was again expressed and evaluated for its ability to cure. Both bottles met the predefined acceptance criterion following each light-exposure condition, demonstrating that the primary packaging provided adequate light protection under the specified test conditions.

The results of the non-clinical performance testing demonstrate that MPa Max adhesive met the predefined acceptance criteria and support the substantial equivalence determination.

21 CFR 807.92(b)(2) – Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicate devices. The substantial equivalence of the MPa Max adhesive is supported by non-clinical performance testing and technological characteristics.

Conclusion

Based on the indications for use, technological characteristics, and the summary of data submitted, Den-Mat Holdings, LLC has determined that the subject device does not raise new questions of safety and effectiveness compared to the predicate devices. Therefore, the proposed subject device is substantially equivalent to the legally marketed predicate devices.