



May 27, 2025

Theodent, LLC  
Andrew Fuselier  
General Manager  
1441 Canal Street  
New Orleans, LA 70112

Re: K243777

Trade/Device Name: Rennou™ Varnish (3% / Spearmint); Rennou™ Varnish (3% / Strawberry);  
Rennou™ Varnish (3% / Cherry); Rennou™ Varnish (3% / Bubble Gum)

Regulation Number: 21 CFR 872.3260

Regulation Name: Cavity Varnish

Regulatory Class: Class II

Product Code: LBH

Dated: May 14, 2025

Received: May 15, 2025

Dear Andrew Fuselier:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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](mailto: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

510(k) Number (if known)  
K1243777

Device Name

Rennou™ Varnish (3% / Spearmint); Rennou™ Varnish (3% / Strawberry); Rennou™ Varnish (3% / Cherry); Rennou™ Varnish (3% / Bubble Gum)

Indications for Use (Describe)

Rennou™ Varnish is indicated for the relief of tooth hypersensitivity through the mechanical occlusion of dentinal tubules.

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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## RENNOU™ VARNISH 510(K) SUMMARY

### 1. SUBMITTER INFORMATION

Name: Theodent, LLC  
Address: 1441 Canal Street  
New Orleans, Louisiana 70112

Phone: (504) 264-5050 (504) 264-1885  
Email: fuselier@theo-corp.com andrew@theo-corp.com  
Contact: Joseph Fuselier Andrew Fuselier

Preparation Date: May 27, 2025

### 2. SUBMITTED DEVICE

Name of Device: Rennou™ Varnish  
Classification Name: Cavity Varnish  
Primary Product Code: 21 CFR 872.3260  
Classification: Class II  
Predicate Device: Colgate® Prevident Varnish (K132109)

### 3. DEVICE DESCRIPTION AND TECHNOLOGICAL CHARACTERISTICS

Rennou™ Varnish is a cavity varnish intended for professional use as a topical application on prepared tooth surfaces. This fluoride-free varnish creates a rosin-based film that prevents penetration of restorative material into the dentinal tissue and provides relief of tooth hypersensitivity by occluding open dentinal tubules. Unit-dose varnish and applicator are packaged together in individual thin, sealed trays. Rennou™ Varnish is only applied by a professional clinician.

Rennou™ Varnish is a topically applied flavored (Spearmint, etc.) compound comprised of natural rosin, ethanol, xylitol, and Rennou™ (a combination of theobromine, calcium acetate, and sodium hydrogen phosphate). The major components are rosin and ethanol, which, when delivered together, efficiently promote a fast-drying film on the tooth surface. The varnish is sweetened with xylitol.

#### 4. INDICATIONS FOR USE

Rennou™ Varnish is indicated for the relief of tooth hypersensitivity through the mechanical occlusion of dentinal tubules.

#### 5. TESTING SUMMARY

Comprehensive laboratory studies evaluated Rennou™ Varnish for performance and biocompatibility. Enamel protection and dentinal hypersensitivity tests on molars and dentin specimens showed effective tubule occlusion, deep penetration, and a smooth surface finish, confirmed by SEM analysis. Cytotoxicity testing per ISO 10993-5 and USP <87> showed acceptable biocompatibility, with Rennou™ Varnish exhibiting a slightly more favorable safety profile when tested directly against the primary predicate device. Additional testing was deemed unnecessary given the device's use of well-established rosin-based varnish technology in the market, documented safety of novel ingredients in dental applications, and substantial equivalence to predicates in both intended use and technological characteristics. The comprehensive risk analysis revealed no new questions of safety or effectiveness, as the device operates through the same mechanical principles as predicates while demonstrating a favorable safety profile, especially for children.

	<b>Rennou™ Varnish</b>	<b>Colgate Prevident Varnish</b>	<b>Colgate Desensitizing Mouthwash</b>	<b>Remedent NV Remesense</b>	<b>Ultradent Flor-Opal Varnish</b>	<b>Novamin Oralief Toothpaste</b>	<b>Comments</b>
<b>Device</b>	Submitted Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device	Reference devices were included to highlight the various approved cavity varnishes containing novel ingredients for occlusion benefit.
<b>510(k) number</b>	K243777	K132109	K140481	K082594	K080249	K080228	
<b>Indication for use(abbreviated)</b>	Treatment of dental hypersensitivity	Treatment of dental hypersensitivity	Treatment of dental hypersensitivity	Treatment of dental hypersensitivity	Treatment of dental hypersensitivity	Treatment of dental hypersensitivity	Indications for Use are consistent amongst all devices.
<b>Product Design</b>	Cavity varnish	Cavity varnish	Mouthwash	Foam Strips	Cavity Varnish	Toothpaste	While product designs differ amongst the devices, our product design is the same as the primary predicate device.
<b>Chemical Composition</b>	Rosin, Ethanol, Xylitol, Theobromine, Calcium Acetate, Sodium Hydrogen Phosphate, Flavor	Rosin, Ethanol, Xylitol, Sodium Fluoride, Hexadecane Phosphate, Citric Acid, Polysorbate 80, Sucralose, Flavor	Water, Glycerin, Sorbitol, Propylene Glycol, Tetrapotassium Pyrophosphate, PEG-40 Hydrogenated Castor Oil, L-Arginine, PVM/MA Copolymer, Polysorbate 20, Tetrasodium Pyrophosphate, Flavor, Benzyl Alcohol, Sodium Fluoride, Menthol,	Glycerin, Water, Dipotassium Oxalate, Flavor, EDTA, Methylparaben, Citric Acid and Saccharin	Rosin, Ethanol, Xylitol, Sodium Fluoride, Hexadecane Phosphate, Citric Acid, Polysorbate 80, Sucralose, Flavor	Calcium Sodium Phosphosilicate, Glycerin, Amorphous Silica, PEG-400, Titanium Dioxide, Sodium Lauryl Sulfate, Flavor, Carbomer, Potassium Acesulfame	Our chemical composition uses a rosin-based formulation for a mechanical occlusion of dentinal tubules, and also includes a novel ingredient to assist in the occlusion, just as the other cleared devices do.

			Sodium Saccharin, Citric Acid, Methylisothiazolinone, CI 42051, CI 17200				
<b>Technological Characteristics</b>	Provides prolonged contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Provides prolonged contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Provides contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Provides contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Provides prolonged contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Provides contact of ingredients with tooth surface; forms protective barrier; releases minerals to enhance tooth structure.	Technologically, our submitted device has the same characteristics as the primary predicate and other reference devices.
<b>Biocompatibility</b>	Yes	Yes	Yes	Yes	Yes	Yes	Any differences between the subject and predicate/reference devices do not raise new safety concerns, as the materials and design are biocompatible and meet established safety standards validated through prior FDA evaluations.

## 6. COMPARISON TO PREDICATE DEVICES

The table above summarizes how Rennou™ Varnish is substantially equivalent to the predicate devices in indication for use, product design, composition of material, technological characteristics, and biocompatibility.

## 7. CONCLUSION

In summary, this submission presents compelling evidence demonstrating that Rennou™ Varnish is substantially equivalent in both safety and effectiveness to its predicate devices. Rigorous testing has shown that Rennou™ Varnish occludes dentinal tubules at a level that meets or exceeds comparable products currently in clinical use. Strict adherence to ISO 10993-5 biocompatibility standards confirms that Rennou™ Varnish is safe when applied as directed by dental professionals.

The technological difference between Rennou™ Varnish and predicate varnishes resides in the formulation. Rennou™ varnish incorporates theobromine and calcium phosphate salts for occlusion benefits. Published scientific literature demonstrates that these ingredients can facilitate mineral deposition on the tooth surface, including the occlusion of dentin tubules. Many predicate cavity varnishes, such as Colgate’s Desensitizing Mouthwash with arginine or Novamin’s bioglass-containing toothpaste, are similar to the Rennou Varnish in that they contain such ingredients for this purpose.

Critically, this product maintains the established indications for use without introducing any new or unforeseen risks, thus preserving the status quo. The data provided in this submission robustly supports the conclusion that Rennou™ Varnish satisfies all criteria for substantial equivalence, ensuring its safe and effective integration into dental practice.