December 5, 2025

Remvia
Nephi Zufelt
Co-Founder
911 Washington Avenue
#500
St. Louis, Missouri 63101

Re: K250743
Trade/Device Name: Remvia NightGuard
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: November 4, 2025
Received: November 4, 2025

Dear Nephi Zufelt:

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) 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.	K250743

Please provide the device trade name(s).

Remvia NightGuard

Please provide your Indications for Use below.

The Remvia NightGuard is indicated for:
• Protection against teeth grinding, bruxism, and jaw clenching
• Short-term pain relief from muscle spasm due to occlusal interference
• Prevention of chronic tension and temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

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)

K250743 - 510(k) Summary

I. Submitter

Remvia
911 Washington Avenue #500
St. Louis, MO, USA, 63101
Phone: 435-260-2124

Contact Person: Mr. Nephi Zufelt
Date Prepared: November 5, 2025

II. Device

Device Proprietary Name:	Remvia NightGuard
Common or Usual Name:	Mouthguard
Classification Name:	Not Classified
Regulation Number:	Not Classified
Product Code:	MQC
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- SleepRight ProRX Custom Dental Guard, K193577, Splintek, Inc.

The following reference device is cited within the submission:

- SleepRight Select-ComfortDental Guard, K212767, Splintek, Inc.

IV. Device Description

The Remvia NightGuard is an intraoral appliance intended to mitigate the harmful effects of nocturnal bruxism. Remvia is retained within the posterior buccal vestibule and retromolar region, using anatomical support from safe, stress-bearing zones. The device does not cover dentition, thereby avoiding continuous occlusal loading and instead creating progressive resistance as clench force increases.

V. Indications for Use

The Remvia NightGuard is indicated for:
• Protection against teeth grinding, bruxism, and jaw clenching
• Short-term pain relief from muscle spasm due to occlusal interference
• Prevention of chronic tension and temporomandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscle.

VI. Comparison of Technological Characteristics

The subject and predicate devices have identical indications for use.

Remvia NightGuard and the predicate device are both adjustable, pre-formed dental guards. The principles of operation are similar as they are intended for passive, intraoral wear during sleep to protect from bruxism and related effects. While the predicate device is designed for full occlusion of maxillary teeth, both the subject device and reference device have similar retention mechanisms; designed for soft tissue retention, including in the buccal vestibule.

While there are differences in device geometry and function, these differences, as shown by the precedent of the reference device and as demonstrated through the performance, do not raise new or different concerns regarding safety or effectiveness of the device.

Remvia NightGuard is similar to the predicate in terms of intended use, function and safety profile. The reference device is used to demonstrate that the technological differences between the subject and predicate device do no raise new questions of safety or effectiveness and the data provided within this submission support that Remvia NightGuard is substantially equivalent to the identified predicate device.

VII. Safety & Performance Data

In support of a substantial equivalence determination, the following design verification testing was performed:

- Material Characterization
    - Ultimate Tensile Strength 3
    - Stress at 50% Elongation
    - Stress at 100% Elongation
    - Elongation at Break
    - Tear Strength
    - Shore Hardness
    - Compression Set 23 °C for 22 hours

  - Compression Set 70 °C for 22 hours
  - Bayshore Resilience
  - Glass transition temperature (Tg)
- Biocompatibility Studies
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Reactivity
  - Acute Systemic Toxicity
  - Muscle Implantation Study

VIII. Conclusion

The information provided with the submission supports that Remvia NightGuard is as safe and effective as the predicate device. Although differences in device geometry and function exist between the subject and predicate device, the reference device demonstrates the clinical precedent for these differences. Coupled with the performance testing completed, these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that Remvia NightGuard is substantially equivalent to the predicate device.