February 25, 2026

GrindGuard Inc.
% Jennifer Day
Regulatory Correspondent
Prime Path Medtech
1321 Upland Dr
Suite 6792
Houston, Texas 77043

Re: K251724
Trade/Device Name: Remi Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: SHI
Dated: June 4, 2025
Received: June 4, 2025

Dear Jennifer Day:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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
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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.	K251724

Please provide the device trade name(s).

Remi Impression Material

Please provide your Indications for Use below.

The Remi Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums to fabricate patient matched nightguards/ mouthguards.

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

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

510(k) Summary (K251724)

A summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

Submitter:	GrindGuard Inc DBA Remi
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Date Prepared:	02/24/2026
Proprietary Name:	Remi Impression Material
Common Name:	Impression Material
Product Code:	SHI
Device Classification:	Class II
Predicate Device:	Accusil Dental Impression Material (K201483)
Reference Device:	Zhengzhou Huaer Impression Material (putty) (K201483)

Device Description:

The Remi Impression Material is an addition-cure silicone impression material (Type 0 putty consistency) composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry.

Indications for Use:

The Remi Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums to fabricate patient matched night guards/mouthguards.

Comparison to Predicate Devices:

Table 1. Predicate Comparison

Specification	***Subject Device:*** *Remi Impression Material*	***Predicate Device:*** *Accusil Putty*	***Reference:*** *Zhengzhou Huaer*
510k	K251724	K213244	K201483
Product Code	SHI	ELW	ELW
Classification Panel	Dental	Dental	Dental
Device Class	Class II	Class II	Class II
Classification	21 CFR 872.3660	21 CFR 872.3660	21 CFR 872.3660
Putty Type	Type 0	Type 0-type 3	Type 0
Material	Vinyl polysiloxane	Vinyl polysiloxane	Vinyl polysiloxane
Mixing Ratio	1:1	1:1	1:1
Anatomical Sites	Mouth/Dentition	Worn on maxillary or mandibular teeth	Mouth/Dentition
Sterile	Non-Sterile	Non-Sterile	Non-Sterile
Fixed/ Removable	Removable	Removable	Removable
Rx/OTC	OTC	Rx	Rx

Specification	***Subject Device:*** *Remi Impression Material*	***Predicate Device:*** *Accusil Putty*	***Reference:*** *Zhengzhou Huaer*
Indication for Use	The Remi Impression Material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums to fabricate patient matched nightguards/mouthguards	Accusil dental impression material is intended to be placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums.	Used for all crown, bridge, and orthodontic impression techniques
Material Type	The Impression Material is a kind of addition-cure rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry. It consists of base and catalyst, in which putty base contains Vinyl polysiloxane, Methylhydrogensiloxane dimethylsiloxane, dimeticone, white oil and silicon. Catalyst mainly contains vinyl polysiloxane, platinum catalyst, dimeticone, white oil and silicon. The product is provided non-sterile	Accusil light, heavy, mono, and bite registration: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and SIH capped polysiloxane Accusil putty: Mixture of vinyl terminated polydimethylsiloxanes and filler materials with platinum catalyst and SIH capped polysiloxane plus softener	The Impression Material is a kind of addition-cure rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry. It consists of base and catalyst, in which putty base contains Vinyl polysiloxane, Methylhydrogensiloxane dimethylsiloxane, dimeticone, white oil and silicon. Catalyst mainly contains vinyl polysiloxane, platinum catalyst, dimeticone, white oil and silicon. The product is provided non-sterile
Working/Processing Time	Up to 240 sec	40-150 sec	Up to 240 sec

Specification	***Subject Device:*** *Remi Impression Material*	***Predicate Device:*** *Accusil Putty*	***Reference:*** *Zhengzhou Huaer*
Setting time/Time in the mouth	60 to 120	60-300 sec	60 to 120
Hardness	58 +/- 2	63-70 Shore A	58 +/- 2
Working humidity	Unknown	50%	Unknown
Dimensional accuracy	>99%	99.9%-99.2%	>99%
Stability (linear dimensional change)	.69	<0.8% typical	.69
Consistency	Type 0 ISO 4823	Type 0-type 3 ISO 4823	Type 0 ISO 4823
Chemical Description	Room temperature vulcanizing 2 components silicone	Room temperature vulcanizing 2 components silicone	Room temperature vulcanizing 2 components silicone

Specification	***Subject Device:*** *Remi Impression Material*	***Predicate Device:*** *Accusil Putty*	***Reference:*** *Zhengzhou Huaer*
Package	Bite registration Impression Trays (2) and 4 small jars; 2 of base and 2 of catalyst.	Accusil bite registration, heavy, light, and monophase come in 2 x 50 ml double cartridges Monophase regular also comes in a 5:1 380ml double cartridges. Accusil putty comes in plastic jars of 150ml and 300ml for both base and catalyst.	Bite registration Impression Trays (2) and 4 small jars; 2 of base and 2 of catalyst.
Method of manipulation	Preformed Impression tray	Preformed Impression tray	Preformed Impression tray

Specification	***Subject Device:*** *Remi Impression Material*	***Predicate Device:*** *Accusil Putty*	***Reference:*** *Zhengzhou Huaer*
Device Description	The Remi Impression Material is an addition-cure rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry. It consists of base and catalyst, in which putty base contains Vinyl polysiloxane, Methylhydrogensiloxane dimethylsiloxane, dimeticone, white oil and silicon. The catalyst mainly contains vinyl polysiloxane, platinum catalyst, dimeticone, white oil and silicon. The product is provided non-sterile.	Accusil Dental Impression Materials are designed for dental applications to define and reproduce the structure of a patient's teeth and gums for producing crowns, bridges, occlusal models and dental implant restorative devices. Base and catalyst components are mixed in an equal ratio 1:1, placed into an impression tray and inserted into the patient's mouth. The material will conform to the patient's dentition and when set will produce a reproduction of the patient's teeth and occlusion.	The Impression Material is a kind of addition-cure rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry. It consists of base and catalyst, in which putty base contains Vinyl polysiloxane, Methylhydrogensiloxane dimethylsiloxane, dimeticone, white oil and silicon. Catalyst mainly contains vinyl polysiloxane, platinum catalyst, dimeticone, white oil and silicon. The product is provided non-sterile
Testing	ISO 4823 & ISO 10993	ISO 4823 & ISO 10993	ISO 4823 & ISO 10993

Intended Use:

The device has the same intended use as the predicate and reference device but includes a change in indications from prescription to over-the-counter (OTC) use. The change in indications comparing to the predicate device, Accusil (K213244) and reference device, Zhengzhou Huaer Impression (putty) (K201483) is supported by the clinical validation study and human factor/usability engineering performance data summarized below.

Technological Features:

The Technological Features (i.e., design, material, chemical composition, principle of operation, energy source, etc.) of the Remi Impression Material is identical to the predicate device. There is no difference between the subject and predicate device thus displaying the substantial equivalence of the subject device.

Performance Testing

There are no formulation/technological changes to the Remi Impression Material subject device vs. the legally marketed Zhengzhou Huaer Impression Material (putty) (K201483) reference device.

Human Factors Testing:

The Remi OTC Impression Kit Human Factors Engineering/Usability Study validation study was designed to demonstrate that untrained lay adults can safely and effectively use the kit at home relying solely on the provided labeling. The study employed an all-comers, consecutive enrollment design in which participants first self-selected using the kit's Instructions for Use, then were independently confirmed as suitable candidates by a physician investigator. Critical tasks evaluated included self-selection, tray sizing, putty mixing, tray loading and seating, maintaining a bite for five minutes, tray removal, and packaging and return of impressions. No professional training or real-time coaching was provided during impression-taking, consistent with the intended OTC home-use environment.

All 35 enrolled participants correctly self-selected as appropriate candidates (100%), with no instances of incorrect self-inclusion or self-exclusion. A minor labeling clarification was identified when 5 participants (14.3%) initially misinterpreted a question about restorative dental work; this was proactively addressed by updating the contraindication language in the IFU. Critical tasks were successfully completed across the study population, with only one subject deviating from the intended tray-use workflow — a recoverable error that was self-corrected without harm. No adverse events occurred throughout the study, and all residual risks were classified as Acceptable or ALARP per the Use-Related Risk Analysis.

Study Participant Outcomes

Outcome	n	%
Enrollment		
Total participants enrolled	35	100%
Self-Selection		
Correctly self-selected as suitable (Category 3)	35	100%
Incorrectly self-excluded — intended users (Category 1)	0	0%
Incorrectly self-included — non-users (Category 2)	0	0%
Experienced confusion on self-selection question (restorative dental work)	5	14.3%
Critical Task Performance		
Successfully completed all critical tasks	35	100%
Experienced minor usability-related issues (non-safety)	6	17.1%
Tray-use workflow deviation (self-corrected, no harm)	1	2.9%
Submitted impressions of insufficient quality (lost to follow-up)	2	5.7%
Safety		
Adverse events	0	0%
Critical-task failures resulting in harm	0	0%

ALARP = As Low As Reasonably Practicable. IFU = Instructions for Use.

Clinical Study

This clinical study evaluated whether at-home dental impressions taken by laypersons using an over-the-counter impression kit produce nightguards of equivalent fit and quality to those made from clinician-collected impressions. The prospective, single-arm, blinded study enrolled 30 subjects across two clinical sites, two investigators, and one independent dentist reviewer. Each subject provided both a self-taken and a dentist-taken impression, and two nightguards were fabricated from each pair — with both subjects and clinicians blinded to the impression source during all fit evaluations. Qualitative evaluation and Quantitative (over 9 points) dimensional analysis were performed on all impressions, 3D models, and nightguards comparing the impressions taken by the dentist to the study subjects.

The results were strongly positive across all endpoints. Quantitatively, the mean dimensional difference between at-home and in-office impressions was only -0.001 mm, with 95% limits of agreement ranging from -0.255 mm to +0.253 mm — well within the pre-defined clinical

tolerance of ±0.30 mm. A Pearson correlation coefficient of 0.99998 confirmed agreement between the two methods. Qualitatively, physicians rated 100% of all nightguards as "A: Excellent Fit," regardless of impression source. Subject ratings were slightly more variable but remained positive, with no nightguard receiving an "F" (unacceptable) rating. No adverse events were reported throughout the study.

The study concluded that OTC impression kits are a clinically acceptable, safe, and effective means for fabricating custom nightguards comparable in quality to those produced from professional impressions — offering a practical alternative for individuals facing cost or access barriers to traditional dental care.

Patient Enrollment and Outcomes

Category	n
Enrollment & Completion	
Total enrolled	35
Lost to follow-up (failed to submit impressions)	2
Included in impression analysis	33
Lost to follow-up (did not return for visit 2)	3
Included in nightguard analysis	30
Demographics	
Female	26 (74%)
Male	9 (26%)
Mean age (range)	43.7 ± 14.0 years (18–71)
Nightguard Fit Ratings (60 total guards evaluated)	
A: Excellent Fit	54 (90%)
B: Good Fit (minor cosmetic issues)	3 (5%)
C: Good Fit (minor, correctable performance issues)	3 (5%)
F: Would not fit / not perform as intended	0 (0%)
Physician Ratings	
Physician ratings — subject impression guards	30/30 A (100%)
Physician ratings — dentist impression guards	30/30 A (100%)
Safety	
Adverse events	0

Conclusion

Based on comparison of indications for use, user population, mechanical, clinical and technological features, the Remi Impression Material is substantially equivalent to the predicate device.