October 20, 2026

Sleepcare, LLC
Eliane Schaefer
Head of Quality and Regulatory Compliance
11858 La Grange Ave. Floor 2
Los Angeles, California 90025

Re: K262421
Trade/Device Name: Daybreak Impression Material
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: SHI
Dated: September 24, 2026
Received: September 24, 2026

Dear Eliane Schaefer:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K262421

Device Name
Daybreak Impression Material

Indications for Use *(Describe)*
The Daybreak 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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Submitter: Sleepcare LLC DBA Daybreak

Company Contact Person: Eliane Schaefer

Address: 11858 La Grange Ave Fl 2, Los Angeles, CA 90025

Phone: (717) 449-4674

Email: eliane@thedaybreak.com

Date Prepared: 06/19/2026

Proprietary Name: Daybreak Impression Material

Common Name: Impression Material

Product Code: SHI

Device Classification: Class II

Predicate Device: Remi Impression Material (K251724)

Device Description:

The Daybreak Impression Material is an addition-cure silicone impression material composed of vinyl polysiloxane and various fillers, with a neutral smell and is applicable to impression in dentistry.

Indications for Use:

The Daybreak 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:*** *Daybreak Impression Material*	***Predicate Device:*** *Remi Impression Material*
510k	N/A	K251724
Product Code	SHI	SHI
Classification Panel	Dental	Dental
Device Class	Class II	Class II
Classification	21 CFR 872.3660	21 CFR 872.3660
Putty Type	Type 0	Type 0
Material	Vinyl polysiloxane	Vinyl polysiloxane
Mixing Ratio	1:1	1:1
Anatomical Sites	Mouth/Dentition	Mouth/Dentition
Sterile	Non-Sterile	Non-Sterile
Fixed/Removable	Removable	Removable
Rx/OTC	OTC	OTC
Indication for Use	The Daybreak 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.	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
Setting Time/Time in Mouth	210 seconds	60 to 120 seconds
Dimensional Accuracy	>99%	>99%
Stability (linear dimensional change)	0.69%	0.69%

Specification	***Subject Device:*** *Daybreak Impression Material*	***Predicate Device:*** *Remi Impression Material*
Consistency	Type 0 ISO 4823	Type 0 ISO 4823
Chemical Description	Room temperature vulcanizing 2 components silicone	Room temperature vulcanizing 2 components silicone
Package	4 Bite registration impression trays, 2 mandibular and 2 maxillary. 8 putty pots, 4 of the base and 4 of the catalyst. Smile stretcher for images of teeth.	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
Device Description	The Daybreak Impression Material is an addition-cure silicone impression material composed of vinyl polysiloxane and various fillers, with a neutral smell and is applicable to impressions in dentistry. It consists of a base and a catalyst, in which the 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.	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.
Testing	ISO 4823 & ISO 10993	ISO 4823 & ISO 10993

Indications for Use:

The indication for use of the subject device is the same as that of the predicate device. Both devices are OTC and use the same materials. This supports the substantial equivalence of the subject device to the predicate device.

Technological Features:

The technological features of the Daybreak Impression Material are substantially similar to the predicate device. Both devices are non-sterile, OTC, Type 0 vinyl polysiloxane impression materials supplied as a two-part base and catalyst system with a 1:1 mixing ratio. Both devices operate by mixing the base and catalyst to form an addition-cure silicone material that is placed in a preformed impression tray and used to reproduce the structure of the patient's teeth and gums for fabrication of patient-matched nightguards/mouthguards.

The subject and predicate devices have the same material type, anatomical contact site, patient-removable use, and general principle of operation. Minor differences in time in mouth and package configuration do not change the intended use, material technology, or mechanism of action, and do not raise new questions of safety or effectiveness because the subject device meets applicable ISO 4823 and ISO 10993 requirements.

Clinical Performance Testing

Clinical performance testing was not conducted because the subject device has the same intended use, technological characteristics, material composition, and principle of operation as the predicate device. Bench performance testing and biocompatibility testing provide sufficient evidence to support substantial equivalence.

Performance Testing

Bench performance testing was conducted in accordance with ISO 4823. Biocompatibility testing was performed in accordance with ISO 10993, as applicable. The results demonstrated that the subject device met the applicable performance and biocompatibility requirements and supports substantial equivalence.

Conclusion

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