May 19, 2025

DOC Brands, Inc.
Eric Mowell
VP, Marketing and Product Development
407 E. Lancaster Avenue
Wayne, Pennsylvania 19087

Re: K250456
Trade/Device Name: Dentemp Pro-Comfort Dental Guard
Regulatory Class: Unclassified
Product Code: OBR
Dated: February 18, 2025
Received: February 18, 2025

Dear Eric Mowell:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250456

Device Name

Dentemp Pro-Comfort Dental Guard

Indications for Use *(Describe)*

Dentemp Pro-Comfort is indicated for protection against nighttime teeth grinding (bruxism). It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.

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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Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

DOC Brands, Inc.'s Dentemp Pro-Comfort Dental Guard (K250456)

Date Prepared: December 28, 2024

510(k)'s Owner's Name, Address, Phone Number:

DOC Brands, Inc.
407 E. Lancaster Avenue
Wayne, PA 19087
Phone: 833-362-2763

Contact Person
Eric Mowell
DOC Brands, Inc., VP Marketing and Product Development

Subject Device
Device Trade Name: Dentemp Pro-Comfort Dental Guard
Device Common Name: mouthguard, dental guard, nightguard
Classification Name: Mouthguard, Over-the-Counter
Product Code: OBR
Regulation Number: Unclassified
Classification Panel: Center for Devices and Radiological Health; Division of Dental and ENT Devices

Predicate Device (Primary Predicate)
DeviceTrade Name: Custom Comfort Nightguard Version 2.
Applicant: DenTek Oral Care, Inc.
Device Common Name: mouthguard, dental guard, nightguard
Classification Name: Mouthguard, Over-the-Counter
Product Code: OBR
Regulation Number: Unclassified
510(k) Number: K091660

Reference Device
Device Trade Name: Ora-GUARD Dental Grind Guard
Applicant: Bite Tech Inc.
Device Common Name: mouthguard, over-the-counter
Classification Name: Mouthguard, Over-the-Counter
Product Code: OBR
Regulation Number: Unclassified
510(k) Number: K150492
Purchased by DOC Brands, Inc. in March of 2021. Now marketed as Dentemp Ora-GUARD.

Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

Subject Device Description

Dentemp Pro-Comfort Dental Guard is an over-the-counter device to be used by lay people for protection against the effects of nighttime teeth grinding. It is manufactured with a two-shot, injection molded process. The first shot is a hard base of Ethylene Methyl Acrylate material (EMA), which contacts the lower tooth surfaces during grinding and prevents grind-through. The second shot is a soft, moldable surface layer of Ethylene Vinyl Acetate material (EVA), which is formed to hug the upper teeth for a comfortable fit. It is a custom fit dental guard, formed to an individual user's mouth by the traditional heat and form fitting technique. It is a full-occlusal guard worn on the upper teeth, providing a barrier to separate the upper and lower teeth and keep them apart while sleeping, thus reducing the damage to teeth caused by bruxism and preventing the noise associated with teeth grinding.

Indications For Use

The Dentemp Pro-Comfort is indicated for protection against nighttime teeth grinding (bruxism). It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.

The predicate device, DenTek Oral Care, Inc.'s Custom Comfort Nightguard Version 2 (K091660), has the exact same indication for use as the subject device. It is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Intended Use

Both the subject device and the predicate device are intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding by acting as a barrier to keep upper and lower teeth separated during sleep. Both guards are intended for in-home use. The intended user population for both guards is age 18 and over.

Technological Characteristics – Materials and Design

The subject device, Dentemp Pro-Comfort Dental Guard, is a full occlusal dental guard. It is custom fit by the user with the traditional heat and form method. It has a hard base of EMA material for grind-through protection and a soft upper layer of EVA which forms easily to the teeth after being heated, due to the guard's channeled design. The hard EMA base is designed with T-Bars which act as fingers to effectively hug the upper teeth and hold the soft EVA material in place during the forming process. By design, the guard effectively acts as a barrier between the teeth and keeps them apart during sleep, thus reducing the damage caused to teeth during nighttime teeth grinding and preventing the noise associated with bruxism.

Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

The predicate device, DenTek's Custom Comfort Nightguard Version 2 (K091660), is a full occlusal dental guard of similar design to the subject device. The predicate device is made of the exact same materials as the subject device. It has a hard base of the same EMA material for grind-through protection and a soft upper layer of the same EVA material which forms easily to the teeth after being heated. The concave curve of the hard base is intended to hold the soft material in place during the forming process. The predicate device has the same intended use as the subject device, to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism by acting as a barrier to keep teeth apart during nighttime bruxing. Thus, the subject device and the predicate device have the exact same technological operating principles. Therefore, the subject device's performance technology is substantially equivalent to that of the predicate device.

The design aspects of the fit technology of the subject device are similar to the reference device, Ora-GUARD Dental Grind Guard. The reference device, cleared as K150492, is an over-the-counter partial occlusal dental guard that also uses T-bars in its hard polycarbonate base to hold the soft EVA material of the surface layer in place during forming. The reference device has the same intended use as the subject device, to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism. Both guards act as a barrier to keep teeth apart during nighttime bruxing. Thus, the subject device and the reference device have the exact same technological operating principles.

Substantial Equivalence Discussion

The following table compares the subject device, Dentemp Pro-Comfort Dental Guard, to the predicate device, DenTek's Custom Comfort Nightguard Version 2, with respect to intended use and technological characteristics. It demonstrates the basis for the determination of substantial equivalence. The reference device, Ora-GUARD Dental Grind Guard, is used for comparison to the special fit technology of the subject device. Any minor differences are explained in the narrative below the table.

510K Summary Table

DOC Brands, Inc.'s Dentemp Pro-Comfort Dental Guard vs DenTek Oral Care, Inc.'s Custom Comfort Nightguard Version 2 K091660

DESIGN	Subject Device Dentemp Pro-Comfort	Predicate Device Custom Comfort Nightguard Version 2 (K091660)	Reference Device Ora-GUARD Dental Grind Guard (K150492)	Comparison Result
Manufacturer	DOC Brands, Inc.	DenTek Oral Care, Inc.	Bite Tech, Inc.	
510(k) #	K250456	K091660	K150492	

Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

DESIGN	Subject Device Dentemp Pro-Comfort	Predicate Device Custom Comfort Nightguard Version 2 (K091660)	Reference Device Ora-GUARD Dental Grind Guard (K150492)	Comparison Result
Device Classification Name	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	Mouthguard, Over-the-Counter	SAME
Regulation #	None Applicable	None Applicable	None Applicable	SAME
Product Code	OBR	OBR	OBR	SAME
Regulatory Class	Not Classified	Not Classified	Not Classified	SAME
Device Description	Full-occlusion, injection molded two-shot, hard base for wear; heat and form moldable surface layer. Worn on upper teeth.	Full-occlusion, injection molded two-shot, hard base for wear; heat and form moldable surface layer. Worn on upper teeth.	Partial-occlusion, injection molded two-shot, hard base for wear; heat and form moldable surface layer. Worn on lower teeth.	Subject Device is Same as Predicate Device
Indications for Use	Pro-Comfort is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.	Custom Comfort Nightguard Version 2 is indicated for use for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.	Ora-GUARD is indicated for bruxism, nighttime teeth grinding, and jaw clenching. It is intended to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism.	Subject Device is Same as Predicate Device
OTC or RX	OTC	OTC	OTC	SAME
User Population	Age 18 and over	Age 18 and over	Age 18 and over	SAME
Technologi-cal Characteris-tics/ Intended Use	Flexible guard intended to be used as a barrier or cushion between upper and lower teeth.	Flexible guard intended to be used as a barrier or cushion between upper and lower teeth.	Flexible guard intended to be used as a barrier or cushion between upper and lower teeth.	SAME
Materials	Comprised of a hard base of EMA copolymer and a soft, moldable surface layer of EVA.	Comprised of a hard base of EMA copolymer and soft, moldable surface layer of EVA.	Comprised of a hard polycarbonate base and a soft, moldable surface layer of EVA	Subject Device is Same as Predicate Device
Fit	Full occlusion, heat and form for custom fit. **Base has T-Bars which hold soft material in channeled surface layer against the teeth during forming for a snug custom fit.**	Full occlusion, heat and form for custom fit. Concave curve of base intended to help hold the soft surface material in place during forming for a snug custom fit.	Posterior occlusion, heat and form for custom fit. **Base has T-Bars which hold soft material in surface layer against the teeth during forming for a snug custom fit.**	[1] Subject Device has Same Fit Technology as Reference Device.

Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

DESIGN	Subject Device Dentemp Pro-Comfort	Predicate Device Custom Comfort Nightguard Version 2 (K091660)	Reference Device Ora-GUARD Dental Grind Guard (K150492)	Comparison Result
Dimensions (l x w x h)	40mm L x 64mm W x 9mm H	38mm L x 63mm W x 9mm H	45mm L x 63mm W x 10mm H	[2] Subject Device is Similar to Predicate Device. .
Weight	7 grams	6 grams	6 grams	[3] Subject Device is Similar to Predicate Device.
Sterilization	Device is not sold sterile	Device is not sold sterile	Device is not sold sterile	SAME
Instructions for Use	Included as insert in retail carton. Instructs how to heat and form the guard.	Included as insert in retail carton. Instructs how to heat and form the guard.	Included as insert in retail carton. Instructs how to heat and form the guard.	SAME
Method of cleaning	Brush with toothpaste and rinse in cool water after use.	Brush with toothpaste or mouthwash and rinse in cool water after each use.	After each use, brush with toothpaste and rinse with cool water.	SAME

The table above identifies a few minor differences between the proposed subject device and the predicate device. The reference device is used for comparison of the special fit technology of the subject device.

1. The fit of the subject device is obtained by using a channeled shape in the soft layer and T-Bars or "fingers" in the hard EMA base material. The T-Bars hold the soft EVA material in place against the user's teeth and gums during the forming process. This is equivalent to the T-bar design of the reference device. The predicate device does not have T-Bars.
2. The subject device is slightly longer and wider than the predicate device with a similar full-occlusion design. This does not affect the safety or effectiveness of the subject device.
3. The subject device weighs 1 gram more than the predicate device, due to its slightly larger length and width dimensions.

In summary, the subject and the predicate device differ only in the design feature used for obtaining a custom fit, and the subject device is slightly longer and wider than the predicate device. The subject device has the exact same design feature as the reference device for obtaining a custom fit. The subject device and the predicate device are made of the exact same material and have the same intended use and technological characteristics, to reduce damage to teeth and prevent the noise associated with teeth grinding and bruxism, by acting as a barrier and keeping teeth apart during grinding. The differences in the subject and predicate do not raise any new concerns about the safety or effectiveness of the subject device, or with substantial equivalence.

Dentemp Pro-Comfort Dental Guard- TRADITIONAL 510(K) SUMMARY

In accordance with section 513(i)(1)(A) of the FDCA, a device is substantially equivalent (SE) when it has the same intended use and technological characteristics as a legally marketed predicate device. As demonstrated in this traditional 510(k), any differences between the subject device and the cited predicate do not raise any new concerns or different questions of safety or effectiveness of the subject device. This application establishes that the subject device is as safe and effective as the predicate device.

Biocompatibility Evaluation

The FDA document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1, Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff was used to assess the biocompatibility and analytical testing requirements for the subject device.

Conclusion of Biocompatibility Evaluation:

The material components of the subject medical device, Dentemp Pro-Comfort Dental Guard, in its final finished form are identical to the material components of DenTek's Custom Comfort Nightguard Version 2, which is the legally marketed predicate device, in formulation, processing, sterilization, and geometry, and no other chemicals have been added.

In addition, the subject medical device, Dentemp Pro-Comfort Dental Guard, in its final finished form is identical to DenTek's Custom Comfort Nightguard Version 2 (K091660), the predicate device, in formulation, processing, sterilization, and geometry and no other chemicals have been added.

Therefore, biocompatibility requirements have been met for the subject device, Dentemp Pro-Comfort Dental Guard. No additional biocompatibility testing was conducted on the subject device by DOC Brands, Inc.

Non-Clinical Performance Testing

Comparative Study

A comparison study of the subject device and reference device demonstrated the performance of the T-Bars made of EMA material in the subject device is equivalent to the performance of the T-Bars made of polycarbonate material in the reference device, in terms of dimensional variation after forming. Therefore, the subject device is operationally equivalent to the reference device and uses the same fit technology to achieve a snug fit.

In-Home Use Test

An In-Home Use Test was conducted on the subject device which validated the overall performance of the subject device in terms of ease of forming, fit, comfort and effectively keeping the teeth apart to prevent bruxing during sleep. The subject device is therefore equivalent to the predicate device in terms of forming, fit, comfort, and functionality.

Conclusion

Dentemp Pro-Comfort Dental Guard has the same indications for use, the same intended use, and the same technological characteristics and principles of operation as the predicate device. The relevant information on biocompatibility, the comparative study and the in-home use test confirm that Dentemp Pro-Comfort fulfills its intended use as safely and effectively as the legally marketed predicate device. Dentemp Pro-Comfort Dental Guard, the subject device, is therefore substantially equivalent to the predicate device, DenTek Oral Care, Inc.'s Custom Comfort Nightguard Version 2 (K091660).