November 28, 2023

Frey Oral Technologies LLC
David Frey
President
433 North Camden Drive, Suite 1070
Beverly Hills, California 90210

Re: K222845
Trade/Device Name: Clench Relief Mouth Piece PRO RX
Regulatory Class: Unclassified
Product Code: MQC, OCO
Dated: October 29, 2023
Received: October 30, 2023

Dear David Frey:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222845

Device Name

Clench Relief Mouth Piece PRO Rx

Indications for Use *(Describe)*

The Clench Relief Mouth Piece PRO RX is indicated for protection of teeth and restorations from injury due to teeth grinding, bruxism, and jaw clenching; temporary relief of TMD and bruxism by reducing muscle tension, and temporary treatment of TMD along with the relief of associated headaches and pains.

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.

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510(k) Summary

I. Submitter

Frey Oral Technologies LLC
433 North Camden Drive
Suite 1070
Beverly Hills, CA 90210

Contact Person: David Frey, DDS
Phone: 818-601-2253
Date Prepared: November 22, 2023

II. Device

Device Proprietary Name:	Clench Relief Mouth Piece PRO RX
Common or Usual Name:	Mouthguard, Prescription
Regulation Number:	N/A
Product Code:	MQC
Device Classification	Unclassified

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Brux-TMD QuickSplint, K111066, MigraTherapy LLC

Reference device:

- SleepRight® Select-Comfort™ Dental Guard, K212767, Splintek, Inc.

IV. Device Description

The Clench Relief Mouth Piece PRO RX is a custom-fit temporary mouthguard which allows the user to achieve a jaw position that alleviates clenching, grinding, and bruxism and help diminish TMD type muscle pain symptoms along with jaw clicking and popping. It allows the prescriber to set and create a new bite plane for the patient that allows the lower jaw to come down and forward from its habitual bite position thus freeing it from its habitual muscle tension. The mouthguard kits contain the Clench Relief Mouthpiece Frame with alignment guide and Clench Relief Fit Material (VPS putty provided as catalyst and base). The mouthpiece frame is packed with mixed putty and placed passively over the lower teeth. The end user must bite on the

alignment guide for 2 minutes while the Clench Relief Fit Material sets. Heating of the mouthguard/putty is not required for molding.

The mouthpiece frame and alignment guide are manufactured from ethylvinyl acetate (EVA). The putty is manufactured from vinyl polysiloxane (VPS) which was previously cleared under K821221.

V. Indications for Use

The Clench Relief Mouth Piece PRO RX is indicated for protection of teeth and restorations from injury due to teeth grinding, bruxism, and jaw clenching; temporary relief of TMD and bruxism by reducing muscle tension, and temporary treatment of TMD along with the relief of associated headaches and pains.

VI. Comparison of Technological Characteristics

The subject and predicate device have the same intended use. Although there are slight differences in the indications for use statements; these differences do not alter the intended use of the subject devices when compared to the predicate device.

The subject and predicate devices are intended for prescription use and are intended for reuse by a single patient.

The table below compares key technological features between the subject and predicate devices.

Technological comparison

Parameter	**Subject Device**	**Brux-TMD QuickSplint (K111066)**
Indications	The Clench Relief Mouth Piece PRO RX is indicated for protection of teeth and restorations from injury due to teeth grinding, bruxism, and jaw clenching; temporary relief of TMD and bruxism by reducing muscle tension, and temporary treatment of TMD along with the relief of associated headaches and pains.	1. Protection of teeth and restorations from injury due to bruxism or clenching. 2. Temporary relief of Temporo Mandibular joint Disorder (TMD) and bruxism by reducing muscle tension. 3. Temporary treatment of Temporal Mandibular Disorder (TMD) along with the relief of associated headaches and pains.
Materials	Ethylene vinyl acetate	Polycarbonate tray

	Vinyl polysiloxane	Vinyl polysiloxane liner
Reusable	Yes, single consumer	Yes, single consumer
Design	Partial coverage (posterior bite plate): preformed mouthpiece. No boiling required.	Partial coverage (anterior bite plate); preformed mouthpiece. No boiling required.

VII. Performance Data

The following studies were performed on the subject, predicate, and/or reference devices in support of the substantial equivalence determination:

- Biocompatibility
  - ISO 10993-5
  - ISO 10993-10
  - ISO 10993-23
- Material hardness per ANSI/ADA 99
- Tear strength per ANSI/ADA 99
- Water sorption per ANSI/ADA 99

VIII. Conclusion

The information provided above supports that the Clench Relief Mouth Piece PRO RX is substantially equivalent to the predicate device. Although minor differences in design and technology exist between the subject and predicate device, the testing supports that these differences do not raise any new questions of safety and effectiveness.

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