June 24, 2021

Charles Sutera, CEO, Officer of Development
Moonwalker Innovations Inc
20 Roosevelt Rd
Medford, Massachusetts 02155

Re: K202523
Trade/Device Name: TMJ Relax
Regulatory Class: Unclassified
Product Code: OCO, MQC
Dated: May 24, 2021
Received: May 26, 2021

Dear Charles Sutera:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202523

Device Name
TMJ Relax

Indications for Use *(Describe)*
A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and;

For the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity

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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Section 5 – 510(k) Summary

1. Submission Sponsor

Moonwalker Innovations Inc
20 Roosevelt Rd
Medford, MA 02155
Phone: +781-487-1111
Contact: Charles Sutera DMD, FAGD, CEO, Officer of Development

2. Submission Correspondent

Moonwalker Innovations Inc
20 Roosevelt Rd
Medford, MA 02155
Phone: +781-487-1111
Contact: Charles Sutera DMD, FAGD, CEO, Officer of Development
Charles.sutera@aestheticsmilereconstruction.com

3. Date Prepared

06/23/2021

4. Device Identification

Trade/Proprietary Name: TMJ Relax™
Common/Usual Name: Mouthguard
Classification Name: Mouthguard, Migraine/Tension Headache; Mouthguard, prescription
Classification Regulation: Unclassified
Product Code: Product Code OCO, MQC
Device Class: Unclassified
Device Use: RX
Classification Panel: Dental

5. Legally Marketed Predicate Device(s)

Primary Predicate: NTI-TSS NTI Tension Suppression System (#K010876)
Reference Device: The Luco Hybrid OSA Appliance (#K160477)

6. Device Description

TMJ Relax™ is durable medical equipment in the form of a mouthguard that is fitted to the teeth that temporarily provides traction on the mandible such that it repositions the mandible to reduce muscle tension. The device is a removeable home use product that a consumer may wear up to 22 hours per day, in other words except when eating or during sports activities.

The TMJ Relax™ system is a single or series of appliances prescribed for patients with a history of a diagnosis of temporomandibular joint disorder and/or migraines/tension headaches. The device is a one-part removeable oral appliance fitted on the mandibular

or maxillary teeth that repositions the mandible while sleeping or during sedentary daytime use. The appliance is patient fitted by using a computer aided manufacturing protocol.

TMJ Relax™ is available by prescription by a healthcare provider (MD, DO, DMD, or DDS) and dispensed directly to the patient by the healthcare provider as durable medical equipment. Impressions and bite registration are required to be taken by a dental healthcare provider.

To fabricate the appliance, maxillary and mandibular impressions are taken by the treating healthcare provider using an additive silicone material of the provider's choice or via digitally scanned impressions. In addition, a bite registration is taken. The patient is instructed to deprogram their bite first, and then a bite registration is taken by the preference of the treating healthcare provider. We suggest taking the bite registration in centric occlusion using a bite fork such as the George Gauge® or via a digitally scanned method. It is preferable to take the bite registration in centric occlusion using a bite fork or another method of disocclusion to account for the resin thickness of the device for most accurate transfer of the bite position indicated by the provider.

The impression samples and bite registration are shipped with provided shipping packaging to our dental lab facility for evaluation, design, and fabrication.

The raw data is obtained using dental laboratory scanners and generated in a computer-aided design software. If raw data is incomplete, the treating healthcare provider is contacted to resubmit new impressions to address the data deficiencies.

When appropriate data is fully submitted, the device is fitted to the consumer's teeth using TMJ Relax's proprietary computer aided design and manufacturing algorithm. The algorithm is consistent for each device manufactured and includes criteria to design a device with the intended mode of action.

The appliance is manufactured via a 3D printer. The manufactured TMJ Relax™ appliance provides traction to the mandible such that it allows the mandible to passively reposition and reduces muscular activity.

The device is dispensed directly to the patient by the healthcare provider to be used according to the recommended indications and instructions for use. The patient wears the initial appliance for approximately 2 weeks which allows the mandible to relax and advance into an initial new mandibular position. A patient follow-up is recommended with the treating healthcare provider after wearing the initial appliance for approximately 2 weeks. The patient is instructed to wear the appliance for at least one hour prior to the followup appointment. The treating healthcare provider has the option to either adjust the device or replace the device with a fabricated device set to a new mandibular position by the treating healthcare provider. If a secondary device is selected, an additional bite registration is taken, mailed by the treating healthcare provider to a

Moonwalker Innovations Inc. dental lab, and a secondary appliance is fabricated to the new mandibular position.

The system may continue in a plurality of adjustments and/or appliances over a period of time which must be directed by the treating healthcare provider. The final appliance in the series may be used long term as durable medical equipment at the direction of the treating healthcare provider.

TMJ Relax™ is an easy to use, reversible method for treatment of medically diagnosed tension-type headaches, and prevention of bruxism and TMJ syndrome by action of reducing of muscular activity.

Special conditions for use statement(s):

a. For at home use.

b. This device is not a substitute for visits to a healthcare provider for recommended screening or appropriate follow-up. It is recommended that users consult with a healthcare provider if there are any questions or concerns about symptoms, and to determine if further treatment is indicated.

c. The etiology of symptoms should be evaluated and confirmed in a clinical setting.

d. The device is intended for users ≥ 18 years old, or those able to be compliant with the protocol as determined by a healthcare provider.

e. The device is intended for people without active caries or periodontal disease, without loose teeth, and with a minimum of 20 existing teeth in the mouth.

7. Indication for Use Statement

A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and;

For the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity

8. Substantial Equivalence Discussion

The comparison chart below provides evidence to facilitate the substantial equivalence determination between TMJ Relax™ to the primary predicate device (K010876) and reference device (K160477) with respect to intended use, technological characteristics, and mode of action.

Device	TMJ Relax™ (Subject Device)	NTI-TSS NTI Tension Suppression System (K010876); Primary Predicate	Luco Hybrid OSA Appliance® (K160477); Reference Device
Product Code	OCO, MQC	OCO	OCO, MQC
Indications for Use	A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and; For the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity	A device to be used in the prophylactic treatment of medically diagnosed migraine pain as well as migraine associated tension-type headaches, by reducing their signs and symptoms through reduction of trigeminally innervated muscular activity, and; For the prevention of bruxism and TMJ syndrome through reduction of trigeminally innervated muscular activity	A device to be used for the treatment of sleep bruxism As an aid in the treatment of associated tension/migraine type headaches in adults
Intended User	Adult in Home Setting	Adult in Home Setting	Adult in Home Setting
Material	Thermoplastic resin	Thermoplastic resin	Thermoplastic resin for tooth bearing surfaces; dental alloy for the framework; stainless steel clasps, wires, and expansion screws
Anatomical sites	Worn on maxillary or mandibular teeth	Worn on maxillary arch involving the upper maxillary central incisors	Worn on maxillary and mandibular teeth
Design	The TMJ Relax is a small intraoral device, which is fitted to a single arch of teeth and has an occlusal surface which is balanced to the new mandibular position and eliminates protrusive/lateral excursive interferences. A healthcare provider monitors symptoms accordingly. The surface is customized by the healthcare provider by manual adjustments or by fabricating a series of appliances from a series of bite registrations to reposition the mandible to the new mandibular	The NTI-tss is a small intraoral device, which is fitted over the two maxillary central incisors and has a dome shaped protrusion, which extends lingually. The dome is customized by the healthcare provider, to act as a single point contact at the incisal embrasure of the two mandibular central incisors, thereby preventing posterior or canine tooth contact. The device does not introduce any chemicals or substances into the patient's system.	Uses wings on a lower appliance to engage blocks of an upper appliance to temporarily hold the mandible forward and disclude the teeth to reposition the mandible to the new mandibular position.

	position as determined by the treating healthcare provider.		
Mechanism of Action	Disocclusion	Disocclusion	Disocclusion
Removeable?	Yes	Yes	Yes
Location of Use	Used by adults at home	Used by adults at home	Used by adults at home
Biocompatibility	Uses a biocompatible acrylic resin (unclassified); Does not use any dyes.	Uses a biocompatible acrylic resin (unclassified); Does not use any dyes.	Uses a biocompatible acrylic resin (unclassified); Does not use any dyes.
Hardness	Hard variation only	Hard variation only	Hard variation only
Sterility	The appliance is delivered non-sterile	The appliance is delivered non-sterile	The appliance is delivered non-sterile
Method of Disinfection	Soap and water; air dry	Soap and water; air dry	Soap and water; air dry

The comparison chart above provides evidence to facilitate the substantial equivalence determination between TMJ Relax™ and our chosen primary predicate, NTI-TSS NTI Tension Suppression System, and the reference device, Luco Hybrid OSA Appliance®.

There is a direct correlation between the Indications for Use Statement/Intended Use of TMJ Relax™, the NTI-TSS NTI Tension Suppression System, and Luco Hybrid OSA Appliance®. Each of the devices are oral appliances used to disocclude the teeth to reposition the mandible. Each of the devices have similar composition and biocompatiability.

The design characteristics between TMJ Relax™, the NTI-TSS NTI Tension Suppression System, and Luco Hybrid OSA Appliance® are substantially equivalent as the primary mode of action is to disocclude the teeth and allow the mandible to reposition to the new mandibular position. The TMJ Relax™ incorporates all active features of the predicate devices related to the intended use.

The primary design difference between the proposed device and the predicate/reference device is where the device sits within the oral cavity. The Luco Hybrid OSA Appliance® sits on both the maxillary and the mandibular teeth, while the TMJ Relax™ sits either the maxillary or mandibular arch, and the primary predicate device, the NTI-TSS NTI Tension Suppression System, sit on the maxillary arch involving the maxillary central incisors. Although the positions of the device within the oral cavity are different, the intent in all of the devices is disocclusion, traction, and repositioning of the mandible to the new mandibular position.

The proposed and predicate devices are patient specific and reuseable for the given patient. TMJ Relax™, the NTI-TSS NTI Tension Suppression System, and the Luco Hybrid OSA Appliance® are made available to patients when critical care is not required. Each of the devices are intended for patients who are willing and capable of managing its use in the home environment.

The TMJ Relax does not raise new questions of safety and effectiveness, and an internal risk analysis supports TMJ Relax is at least as safe and effective as both predicate devices.

All these facts provide evidence to facilitate the substantial equivalence determination between TMJ Relax™ and the primary predicate device, NTI-TSS NTI Tension Suppression System (K010876) and the reference device, the Luco Hybrid OSA Appliance® (K160477).

9. Non-Clinical Performance Data

During the development of TMJ Relax™ Standards ISO 20795-2, ANSI 139-2012, and ISO 10993-1 were carefully considered to ensure compliance. As per the 10993-1 guidance document, the TMJ Relax™ device is classified as a surface contacting device with the mucosal membrane for long term use > 30 days. The contact duration is based on ISO 10993-1, Clause 5.3: medical devices whose cumulative sum of single, multiple or repeated contact time exceeds 30 d.

The TMJ Relax device complies with all applicable standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for home use for many years with a proven safety and efficacy for the use of the device. The subject device is identical and/or substantially equivalent to the predicate devices, and introduces no new risks or concerns compared to the predicates.

11. Statement of Substantial Equivalence

The TMJ Relax™ has the same or similar intended use as the primary predicate and the reference device and any technological differences between the TMJ Relax™ and the predicate/reference devices do not raise any questions regarding TMJ Relax™ safety and effectiveness.

The proposed labeling states intended uses, selection criteria, results of the product, directions for proper use, and warnings in such terms that the prescribed product would be understood and used properly by the ordinary individual including individuals of low comprehension under customary conditions of purchase and use. A healthcare provider user manual will be provided to healthcare providers and a patient user manual will be

provided within the product packaging, also will be available via downloadable PDF format which can be viewed, saved, or printed. Further information, instructions, and questions will be available from the prescribing healthcare provider. Information included details how dental healthcare providers should take impressions to fabricate the device and how to follow-up care. Patient user manual details how to properly use the device, how to clean the device, describes common expectations, and how to properly evaluate the need for follow up care with a healthcare provider.

The information provided in this submission supports the substantial equivalence to the predicate device and that the system is safe and effective for the users/operators in the home setting.