June 7, 2019

Zephyr Sleep Technologies, Inc.
Sabina Bruehlmann
Director, Technology
102, 701 64 Ave SE
Calgary, T2H 2C3 Ca

Re: K190051
Trade/Device Name: TD Clip
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: April 30, 2019
Received: May 1, 2019

Dear Sabina Bruehlmann:

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,

Srinivas Nandkumar, Ph.D.
Assistant Director
DHT1B: Division of Dental 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)*
K190051

Device Name
TD Clip

Indications for Use *(Describe)*
The TD Clip is intended to be used with MATRx or MATRx plus Titration Trays to form a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The device is intended to be fitted with assistance from a healthcare professional and used during sleep for a total of less than 30 nights.

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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ZEPHYR Sleep Technologies
#102, 701 - 64th Avenue SE, Calgary, AB, T2H 2C3, Canada

## Section 5 – 510k Summary – TD Clip

| | |
|---|---|
| Date: | January 9, 2019 |
| Manufacturer Name: | Zephyr Sleep Technologies, Inc. |
| Contact Name: | Sabina Bruehlmann, PhD |
| Title: | Director, Technology |
| Postal Address: | #102, 701 64th Ave SE<br>Calgary, Alberta, Canada<br>T2H-2C3 |
| Phone Number: | 587-332-0285 |
| Fax Number: | 587-332-0208 |
| Establishment Registration Number: | 3008960597 |
| Device Proprietary Name: | TD Clip |
| Classification Name: | CFR 872.5570 |
| Classification Code: | Class II |
| Product Code: | LRK (anti-snoring device) |
| Predicate Device: | Apnea Guard (K111110) |
| Reference Devices: | MATRx plus (DEN170090)<br>MATRx (K103704)<br>Brux-TMD QuickSplint (K111066) |

**Device Description:**

The TD Clip is a temporary oral appliance. The patient uses the temporary oral appliance to alleviate mild to moderate obstructive sleep apnea and/or snoring while waiting for a custom oral appliance to be manufactured.

The dentist fabricates temporary titration trays consisting of upper and lower dental trays. The trays are custom fit to the patient using polyvinyl siloxane impression material.

The healthcare provider may use the clip assembly to fasten the titration trays at the target therapeutic position to form the TD Clip temporary oral appliance. Patients may use the temporary oral appliance as treatment while waiting for their custom oral appliance. Adjustment of the position requires the setting of a new TD Clip by the healthcare professional.

In the expected workflow, the patient first completes an OA Assessment study with the MATRx or MATRx plus system. The healthcare provider then takes the titration trays used in the overnight OA Assessment study and fastens them at the intended target protrusive position for temporary treatment.

**Indications for Use:**

The TD Clip is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The device is intended to be fitted with assistance from a healthcare professional and used during sleep for less than 30 nights.

**Patient Population:**

The TD Clip is intended to be used on adult patients upon referral from their healthcare provider.

**Contraindications:**

The device is contraindicated for patients who:

- have central sleep apnea
- have loose teeth or advanced periodontal disease
- have full dentures or dental implants
- have temporomandibular joint (TMJ) dysfunction syndrome
- have severe respiratory disorders
- are under 18 years of age

**Comparison to Predicate Device:**

The TD Clip is substantially equivalent to the predicate, Apnea Guard. The following table provides a comparison of the intended use and technological features of the subject, predicate, and reference devices.

| | Primary Predicate | Reference Device | Subject Device | Substantial Equivalence Discussion |
|---|---|---|---|---|
| **Proprietary Name** | **Apnea Guard** | **MATRx plus** | **TD Clip** | |
| **510(k) Number** | **K111110** | **DEN170090** | **--** | |
| **Manufacturer** | **Advanced Brain Monitoring, Inc.** | **Zephyr Sleep Technologies, Inc.** | **Zephyr Sleep Technologies, Inc.** | |
| **Indications for Use** | | | | |
| | The Apnea Guard is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The Apnea Guard is intended to be fitted with assistance from a healthcare professional, and used during sleep for less than 30 nights. | The MATRx plus device may also be used with an automated mandibular positioner that uses feedback control to record changes in the patient's respiratory status related to repositioning of the mandible during an overnight study. MATRx plus uses these recordings to produce a report for the HCP that can be used to prospectively identify patients with mild to moderate obstructive sleep apnea who may be suitable for therapy with an oral appliance and to recommend a target mandibular position.<br>The use of the device does not replace the need for follow-up testing to determine the initial and ongoing effectiveness of the therapy as recommended by clinical practice | The TD Clip is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The device is intended to be fitted with assistance from a healthcare professional and used during sleep for a total of less than 30 nights. | The indications for use of the subject device are identical to those of the primary predicate. |

| | Primary Predicate | Reference Device | Subject Device | Substantial Equivalence Discussion |
|---|---|---|---|---|
| **Proprietary Name** | **Apnea Guard** | **MATRx plus** | **TD Clip** | |
| **510(k) Number** | **K111110** | **DEN170090** | **--** | |
| **Manufacturer** | **Advanced Brain Monitoring, Inc.** | **Zephyr Sleep Technologies, Inc.** | **Zephyr Sleep Technologies, Inc.** | |
| | | guidelines. | | |
| **Use Environment** | | | | |
| Intended for nighttime use | Yes | | | Identical |
| Indicated for use at home or in sleep laboratories | Yes | | | |
| In-use claim | Less than 30 days | Duration of Titration study (max: 3 days) | Less than 30 days (Including titration study use) | Identical to predicate – total use < 30 days |
| **Contraindications** | | | | |
| | Missing, loose, infected teeth, temporary crowns or fillings, TMJ dysfunction syndrome | Loose teeth, advanced periodontal disease, full dentures/implants, TMJ dysfunction syndrome, central sleep apnea, severe respiratory disorders, under 18 years of age | | Substantially equivalent – devices are intended for use in adults with mild to moderate obstructive sleep apnea who have sufficient dentition and no relevant comorbidities |
| **Technological Characteristics** | | | | |
| **Design** | | | | |
| Operating Principle – Mandibular Advancement | Yes | | | Identical |
| Separate upper and lower tray pieces | Yes | | | |
| Placed in patient's mouth each evening | Yes | | | |
| Mechanism of tray fastening | Same (Connected via brackets extending from the oral cavity with directional guidance from rails) | | | |
| Permitted lateral and/or vertical jaw movement | Yes | | | |
| Method of retention – impression material | Yes | | | |
| Customized fit for each patient | Yes | | | |
| Adjustment mechanism | Yes | | | |

| | Primary Predicate | Reference Device | Subject Device | Substantial Equivalence Discussion |
|---|---|---|---|---|
| **Proprietary Name** | **Apnea Guard** | **MATRx plus** | **TD Clip** | |
| **510(k) Number** | **K111110** | **DEN170090** | **--** | |
| **Manufacturer** | **Advanced Brain Monitoring, Inc.** | **Zephyr Sleep Technologies, Inc.** | **Zephyr Sleep Technologies, Inc.** | |
| Method of fixing the position | Pin connection through one of several slots | Pin connection to a motorized mandibular positioner | Pin connection to the TD clip device; pin used to fix in place | Substantially equivalent – pin used to secure protrusive level |
| Dental tray shape | Same (Full arch, lingual and buccal walls to hold impression material) | | | Identical |
| Dental tray sizing | One size fits all. Adjustable arch width. | Available in 2 sizes (medium and large). Adjustable arch width. | | Substantially equivalent – multiple sizes in subject device accommodate full range of arch widths |
| Fastening resolution | 1.0 mm | 0.5 mm | | Substantially equivalent – ability to fasten trays at a clinically meaningful resolution |
| Can be adjusted or refit | Yes – with assistance from a healthcare professional | | | Identical |
| **Materials** | | | | |
| Biocompatibility testing | Same (Testing according to 10993-1) | | | Identical |
| Impression material composition | Polyvinyl siloxane impression material | | | Substantially equivalent – standard dental impression material |
| Patient instructions for cleaning | Same (cleaned by rinsing with water) | | | Identical |
| Single-patient multi-use | Yes | | | Identical |
| Sterility | Same (not provided sterile) | | | Identical |
| **Performance Specification** | | | | |
| Holds mandible in protrusion for the duration of the night | Same | | | Identical |
| Adjustment range | 26 mm (8 mm retrognathic to 18 mm prognathic) | 20 mm (6 mm retrognathic to 14 mm prognathic) | | Substantially equivalent; identical to reference device. Adjustment range of subject device is identical to that |

| | Primary Predicate | Reference Device | Subject Device | Substantial Equivalence Discussion |
|---|---|---|---|---|
| **Proprietary Name** | **Apnea Guard** | **MATRx plus** | **TD Clip** | |
| **510(k) Number** | **K111110** | **DEN170090** | **--** | |
| **Manufacturer** | **Advanced Brain Monitoring, Inc.** | **Zephyr Sleep Technologies, Inc.** | **Zephyr Sleep Technologies, Inc.** | |
| | | | | available in the OA Assessment study. |

The subject and predicate devices have equivalent indications for use, target populations, in-use claims, and contraindications. Both devices are prescription use and are fitted with assistance from a healthcare professional. Both the subject and predicate device operate by providing mandibular advancement to the patient via separate upper and lower trays that are placed in the mouth by the patient each evening. Both devices use brackets that extend from the oral cavity. The tray design, use of polyvinyl siloxane impression material, and instructions for cleaning are equivalent between the subject and predicate devices. The Titration Trays and impression material used in the TD Clip device are the same as those previously cleared for use for the MATRx (K103704) and MATRx plus (DEN170090) devices. The adjustment range of the TD Clip device, though smaller than that of the predicate, is identical to that of the reference device.

While the fastening system of both devices rely on pins, the design differs slightly between the two devices. The Apnea Guard predicate device uses pin connections through one of several slots, while the TD Clip uses a pin to connect the clip to the Titration Trays, and a pin in combination with a serrated interface to hold the position.

**Performance Testing**

All materials in contact with the mucosal membrane were assessed and tested in accordance with ISO 10993-1 and the associated FDA guidance, *Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing within a Risk Management Process'*" issued June 16, 2016.

Bench testing of the assembled device simulating mechanical and environmental use conditions was conducted to ensure that the device performs as intended and is safe and effective. The following bench testing was conducted:

| Test | Test Description |
|---|---|
| Intraoral Material Performance | The trays and impression material were evaluated under simulated aging, including environment conditions and representative worst-case loading schemes to ensure there was no presence or increased risk of breakage that could lead to an unacceptable harm over the maximal study length (30 nights of use). |

| | |
|---|---|
| TD Clip Performance | The TD Clip was evaluated under repeated use and exposed to normal sleep forces over 30 nights of use, including static and cyclic loading under worst-case use, to ensure that it maintained the set protrusive positioning. |
| Tray Removal Simulation | The TD Clip Titration Trays were evaluated to ensure that 100% of users were able to remove the Titration Trays from their mouth quickly and without causing injury to themselves or the Titration Trays. |

Clinical testing was not performed as the device has no technological differences from the predicate.

During risk management and performance testing, no new risks were identified. The risk management concluded that the TD Clip had no unacceptable risks.

**Conclusion:**

Based on the information provided in this 510(k) premarket notification, the TD Clip is substantially equivalent in terms of safety and efficacy to the predicate device identified above.