



August 23, 2018

Zephyr Sleep Technologies
Sabina Bruehlmann
Director, Technology
#102, 701 64th Ave SE
Calgary, Alberta Canada
T2H 2C3

Re: DEN170090

Trade/Device Name: MATRx plus
Regulation Number: 21 CFR 872.5571
Regulation Name: Auto titration device for oral appliances
Regulatory Class: Class II
Product Code: QCJ
Dated: December 18, 2017
Received: December 21, 2017

Dear Sabina Bruehlmann:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the MATRx plus, a prescription device under 21 CFR Part 801.109 with the following additional indications for use:

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.

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 guidelines.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the MATRx plus, and substantially equivalent devices of this generic type, into Class II under the generic name auto titration device for oral appliances.

FDA identifies this generic type of device as:

Auto titration device for oral appliances. An auto-titration device for oral appliances is a prescription home use device that determines a target position to be used for a final oral appliance for the reduction of snoring and mild to moderate obstructive sleep apnea.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 23, 2016 automatically classifying the MATRx plus in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II.

On December 21, 2017, FDA received your De Novo requesting classification of the MATRx plus. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the MATRx plus into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the MATRx plus can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Infection	Reprocessing validation Labeling
Intraoral/TMJ injury, irritation or pain due to: <ul style="list-style-type: none"> ▪ Use error ▪ Algorithm-directed positioning ▪ Interference with other devices ▪ Device electrical failure 	Clinical performance testing Human factors assessment Non-clinical performance testing Software verification, validation, and hazard analysis Electrical safety testing Electromagnetic compatibility (EMC) testing Wireless coexistence testing

Incorrect titration level due to use error	Human factors assessment Labeling
Disruption of sleep	Labeling
Temporary change in bite or dentition	Labeling

In combination with the general controls of the FD&C Act, the auto titration device for oral appliances is subject to the following special controls:

- (1) Clinical performance testing must evaluate the following:
 - (i) Performance characteristics of the algorithm; and
 - (ii) All adverse events.
- (2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions for use, including the following:
 - (i) Validation of the closed loop algorithm;
 - (ii) Mechanical integrity over the expected use life;
 - (iii) Characterization of maximum force, distance, and speed of device movement; and
 - (iv) Movement accuracy of intraoral components.
- (3) Performance testing must demonstrate the wireless compatibility, electrical safety, and electromagnetic compatibility of the device in its intended use environment.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (6) Performance data must validate the reprocessing instructions for any reusable components.
- (7) Patient labeling must include:
 - (i) Information on device use, including placement of sensors and mouthpieces;
 - (ii) A description of all alarms; and
 - (iii) Instructions for reprocessing any reusable components.
- (8) A human factors assessment must evaluate simulated use of the device in a home use setting.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the auto titration device for oral appliances they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Anita Belani, DDS at 301-796-3944.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health