January 12, 2024

Bone Health Technologies, Inc.
% Dave McGurl
Vice President, Regulatory Affairs - Orthopedics
MCRA, LLC
803 7th Street NW, Floor 3
Washington, District of Columbia 20001

Re: DEN230015
Trade/Device Name: Osteoboost Belt
Regulation Number: 21 CFR 888.5895
Regulation Name: Wearable vibration device for orthopedic use
Regulatory Class: Class II
Product Code: QZO
Dated: February 17, 2023
Received: February 17, 2023

Dear Dave McGurl:

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 Osteoboost Belt, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Osteoboost Belt is indicated to reduce the decline in bone strength and volumetric bone density, as assessed via CT (computed tomography) scans that were analyzed using the O.N. Diagnostics VirtuOst estimate of vertebral bone strength and density in postmenopausal women with osteopenia of the lumbar vertebrae or total hip as diagnosed via dual x-ray absorptiometry with a bone mineral density T-score between -1.0 and -2.49.

- The clinical effects have only been observed for the duration of the clinical study performed to support the indications for use (1 year).
- Fracture risk was not evaluated in the clinical study to support the indications for use, so it is not known how the treatment effects correlate with fracture risk.
- The clinical effects have been demonstrated only for those who used the device as indicated.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Osteoboost Belt, and substantially equivalent devices of this generic type, into Class II under the generic name wearable vibration device for orthopedic use.

FDA identifies this generic type of device as:

> **Wearable vibration device for orthopedic use:** A wearable vibration device for orthopedic use is a wearable device that uses mechanical vibrations, targeted to specific regions of the skeleton, to reduce loss of bone strength or bone mineral density.

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.

On February 17, 2023, FDA received your De Novo requesting classification of the Osteoboost Belt. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Osteoboost Belt 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 Osteoboost Belt 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:

| **Risks to Health** | **Mitigation Measures** |
|---|---|
| Accelerated loss of bone strength and bone mineral density resulting from application of inappropriate magnitude and/or frequency of vibration | Clinical performance testing<br>Non-clinical performance testing<br>Software verification, validation, and hazard analysis<br>Electromagnetic compatibility testing<br>Labeling |
| Adverse tissue reaction | Biocompatibility evaluation |
| Patient injury due to electrical, mechanical, or thermal hazards | Electrical safety testing<br>Electromagnetic compatibility testing<br>Mechanical and thermal safety testing<br>Software verification, validation, and hazard analysis<br>Labeling |
| Adverse effects on the patient including regional pain, dizziness, blurred vision, muscle weakness, | Clinical performance testing<br>Labeling |

| | |
|---|---|
| difficulty with balance, headache, and nausea | |
| User error leading to ineffective reduction in loss of bone strength or bone mineral density | Clinical performance testing<br>Human factors/usability evaluation<br>Labeling |

In combination with the general controls of the FD&C Act, the wearable vibration device for orthopedic use is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate the reduction in loss of bone strength or bone mineral density. Testing must evaluate patient risks, including regional pain, dizziness, blurred vision, muscle weakness, difficulty with balance, headache, and nausea. The testing must include a minimum of 1 year follow up.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be provided:
   (i) Characterization of the designed outputs of the device;
   (ii) Demonstration of the reliability and reproducibility of device output; and
   (iii) Validation that vibration characteristics received by the patient are within safe physiologic limits.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must be provided to demonstrate the electrical safety, mechanical safety, thermal safety, battery safety, and electromagnetic compatibility of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Human factors or usability evaluation must demonstrate that the user can correctly use the device, based solely on reading the directions for use.

(7) Labeling must include the following:
   (i) A summary of the clinical performance testing with the device, including clinical outcomes and observed adverse events;
   (ii) Information regarding limitations of the clinical significance of the clinical performance testing;
   (iii) Instructions on duration and frequency of use, and when to discontinue use of the device; and
   (iv) Instructions for device maintenance, including appropriate cleaning of any reusable components and safe disposal of the device.

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

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.

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 wearable vibration device for orthopedic use 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/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 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Sai Deepa Rayaprolu, M.S. at SaiDeepa.Rayaprolu@fda.hhs.gov.

Sincerely,

Raquel A. Peat -S

CAPT Raquel Peat, Ph.D., M.P.H., USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health