August 16, 2023

BlueWind Medical Ltd.
Roni Diaz
Vice President, Clinical & Regulatory Affairs
6 Maskit Street
Herzliya, 4614002
Israel

Re: DEN220073
Trade/Device Name: Revi System
Regulation Number: 21 CFR 876.5305
Regulation Name: Implanted tibial electrical urinary continence device
Regulatory Class: Class II
Product Code: QXM
Dated: October 5, 2022
Received: October 5, 2022

Dear Roni Diaz:

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

> The Revi System is indicated for the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Revi System, and substantially equivalent devices of this generic type, into Class II under the generic name implanted tibial electrical urinary continence device.

FDA identifies this generic type of device as:

> **Implanted tibial electrical urinary continence device**. An implanted tibial electrical urinary continence device is an implanted prescription device that receives power from a non-implanted external power source to provide electrical stimulation of the tibial nerve in proximity to the ankle. The device is intended for the treatment of overactive bladder related symptoms of urge urinary incontinence, urinary urgency, urinary frequency and nocturia.

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 October 5, 2022, FDA received your De Novo requesting classification of the Revi System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Revi System 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 Revi System 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**
Overstimulation leading to nerve/tissue damage	Non-clinical performance testing Electromagnetic compatibility testing Electrical safety testing Software verification, validation, and hazard analysis Wireless coexistence testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Infection	Sterilization validation Shelf-life testing Labeling
Thermal injury	Non-clinical performance testing Thermal safety testing Electrical safety testing
Interference with other medical devices	Electromagnetic compatibility testing Magnetic resonance compatibility testing Electrical safety testing Software verification, validation and hazard analysis Wireless coexistence testing Labeling
Pain and discomfort	Non-clinical performance testing Electrical safety testing Labeling
Electrical shock or stimulation of non-target tissue	Electrical safety testing Electromagnetic compatibility testing Labeling

Mechanical injury to device or tissue/nerves	Non-clinical performance testing Labeling
Undesired fluid retention due to use in inappropriate population	Labeling

In combination with the general controls of the FD&C Act, the implanted tibial electrical urinary continence device is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following testing must be conducted:
  (i) Electrical performance testing of the device must be conducted to validate the specified electrical output and duration of stimulation of the device; and
  (ii) Testing must verify the implant can withstand clinically relevant forces during and after implantation.
(2) The patient-contacting components of the device must be demonstrated to be biocompatible.
(3) Performance data must demonstrate the sterility of the patient-contacting components of the device.
(4) Performance data must support the shelf life of the device by demonstrating continued sterility of patient contacting components, package integrity, and device functionality over the identified shelf life.
(5) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, thermal safety and wireless performance of the device.
(6) Software verification, validation, and hazard analysis must be performed.
(7) Performance testing must evaluate the compatibility of the device in a magnetic resonance environment.
(8) Labeling for the device must include:
  (i) A contraindication against use during pregnancy;
  (ii) A contraindication against using the device in men who have Benign Prostatic Hyperplasia (BPH) or other lower urinary tract obstructions;
  (iii) A detailed summary of the device technical parameters and the typical course of treatment;
  (iv) Device- and procedure-related adverse events pertinent to use of the device; and
  (v) A shelf life for any sterile components.
(9) Patient labeling must include:
  (i) Post-operative care instructions to avoid infection and inflammation of the surgical site;
  (ii) Instructions to avoid overstimulation related nerve/tissue damage;
  (iii) Instructions to avoid mechanical injuries to nerve/tissue caused by the implanted component;
  (iv) Instructions for reprocessing/cleaning of any reusable components;
  (v) Clinical performance reported by relevant subgroups;
  (vi) The risks and benefits associated with use of the device;
  (vii) Information on the typical course of treatment;
  (viii) Instructions to avoid pain and discomfort; and
  (ix) Instructions to avoid interference with other medical devices.

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 implanted tibial electrical urinary continence device 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 Nabamita Pal at nabamita.pal@fda.hhs.gov

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health