May 2, 2024

BlueWind Medical Ltd.
Jason Woehrle
Director Regulatory Affairs
6 Maskit Street
Herzliya, 4614002
ISRAEL

Re: K240037
Trade/Device Name: Revi™ System
Regulation Number: 21 CFR 876.5305
Regulation Name: Implanted Tibial Electrical Urinary Continence Device
Regulatory Class: II
Product Code: QXM
Dated: January 4, 2024
Received: January 5, 2024

Dear Jason Woehrle:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sharon M. Andrews -S

Sharon M. Andrews
Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240037

Device Name

Revi™ System

Indications for Use *(Describe)*

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

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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510(k) Summary

I. Company:

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Israel

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Date Prepared: May 1, 2024

II. Proprietary Trade Name: Revi™ System

III. Common or Usual Name: Implantable tibial electrical urinary continence device

IV. Classification Name: Implantable tibial electrical urinary continence device (21 CFR 876.5305)

V. Classification: Class II

VI. Product Code: QXM

VII. Product Description:

The Revi™ System is an implanted tibial electrical urinary continence device that wirelessly receives power from a non-implanted external wearable unit to provide electrical stimulation of the tibial nerve in proximity to the ankle. The device is intended for the treatment of urge urinary incontinence, alone or in combination with urinary urgency. The implantable device is implanted in the vicinity of the tibial neurovascular bundle. The treatment effect of the system is achieved by the implantable wireless neurostimulation component, which sends pulses to the tibial nerve when energized by the wearable unit transmitted power. The electrical pulses stimulate the nerve along the leg, reaching the sacral plexus and entering the spinal cord. This stimulation has the power to modulate nerve function, relieving symptoms.

VIII. 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.

IX. Summary of the Technological Characteristics

Description	**Subject Device** Revi System with v4.3 software (K240037)	**Predicate Device** Revi System with v4.1.2.5 software (DEN220073)
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.	The Revi System is indicated for the treatment of patients with symptoms of urgency incontinence alone or in combination with urinary urgency.
Principles of Operation	Implanted device received power from non- implanted external wearable device providing electrical stimulation to tibial nerve in proximity to ankle.	Implanted device received power from non- implanted external wearable device providing electrical stimulation to tibial nerve in proximity to ankle.
Treatment Programs	Ability to store up to 4 treatment programs	Ability to store up to 2 treatment programs

The modified Revi System with v4.3 software is identical to the predicate Revi System with v4.1.2.5 software in terms of indications for use, intended use, operational principle, design and is equivalent in terms of software function. The differences between the modified Revi System and predicate device do not raise different questions of safety and effectiveness.

X. Identification of Legally Marketed Devices

Revi System (DEN220073)

Note: The predicate device has not been subject to a design-related recall.

XI. Discussion of the Performance Testing

Non-clinical benchtop testing was conducted to evaluate the performance characteristics of the modified Revi System.

Verification testing to ensure identical specification to predicate included the following:

- stimulation frequency control to ensure range and accuracy compliance with specification
- charging mode protection to ensure protection operates in compliance with specification
- system performance to ensure system performance in compliance with technical specification
- software verification to verify software requirements, including cybersecurity testing

A human factors/usability evaluation of the Revi™ System with v4.3 software and a gap analysis with the predicate device found that no new critical tasks were introduced by the subject device.

XII. Conclusion

The Revi™ System with v4.3 software has been shown through testing and comparison to be substantially equivalent to the identified predicate device.