December 12, 2025

BlueWind Medical Ltd.
℅ Elissa Burg
CEO / Regulatory Consultant
BioVision Ltd.
Perach Halilach 183
Had - Nes, 1295000
ISRAEL

Re: K252391
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: July 31, 2025
Received: November 12, 2025

Dear Elissa Burg:

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: The Center for Devices and Radiological Health (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 Food and Drug Administration (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSICA K. NGUYEN -S

Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
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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)*

K252391

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

BlueWind Medical Ltd.'s Revi System

I. Company:

BlueWind Medical Ltd.
6 Maskit Street
Herzliya, 4614002
Israel

Contact: Elissa Burg
Regulatory Consultant
BioVision Ltd.
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Israel 1295000
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Email:elissa@biovision.co.il

Date Prepared: December 11, 2025

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. Predicate Device: Revi System (K240037)

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

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.

Note: The indications for use statement is identical to the indications for use statement of the predicate device.

IX. 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 urgency 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 is theorized to have the power to modulate nerve function, relieving symptoms.

The modifications reported in this 510(k) submission include introducing an updated Wearable Unit, an associated software update to support the updated Wearable Unit and related labeling. These modifications do not affect the implantable component of the Revi System or the indications for use.

X. Comparison of Technological Characteristics with Predicate

Description	**Subject Device** Revi System	**Predicate Device** Revi System (K240037)
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.
System Components	• Implant – neurostimulator • Rechargeable Wearable Unit - non-implanted, rechargeable, powers the Implant to provide electrical stimulation • Clinician Programmer (CP) - proprietary application that interfaces with the Wearable Unit and Cloud	• Implant – neurostimulator • Rechargeable Wearable Unit - non-implanted, rechargeable, powers the Implant to provide electrical stimulation • Clinician Programmer (CP) - proprietary application that interfaces with the Wearable Unit and Cloud

Description	**Subject Device** Revi System	**Predicate Device** Revi System (K240037)
	• HealthGo Micro Hub - communicates with the Wearable Unit to acquire data and transmit to the Cloud	• HealthGo Micro Hub – communicates with the Wearable Unit to acquire data and transmit to the Cloud
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.
Energy Source	Wearable Unit powered by internal rechargeable battery that is replaceable.	Wearable Unit powered by internal rechargeable battery.
Software Version	v5.0.0.3	v4.3
Intended population	Adult Users	Adult Users
Use Environment	Rx only - Prescription Use	Rx only - Prescription Use
Materials	*Implant* Zirconia ceramic, titanium, and gold capsule, coated with perylene; platinum- iridium electrodes, and silicone suture wings. *Wearable Unit* Polycarbonate and silicone covered with fabric	*Implant* Zirconia ceramic, titanium, and gold capsule, coated with perylene; platinum- iridium electrodes, and silicone suture wings. *Wearable Unit* Polycarbonate and silicone covered with fabric
Battery component	Replaceable battery	Non-replaceable battery
User Interface (UI)	Three enlarged buttons with four separate, shape-specific LED indicators in a linear arrangement	Three buttons with a single muti-color LED (red/yellow/green) in a triangular layout
Device Power Consumption	Enhanced power consumption via internal circuit and firmware improvements	Same device power consumption as DEN220073
Design for Manufacturability and Scalability	• Replacement of electronic components with newer equivalents • Integration of printed circuit boards • Redesigned enclosure using plastic injection molding	Same device design and manufacturing process as DEN220073

XI. Performance Testing

Non-clinical benchtop testing was conducted to evaluate the performance characteristics of the modified Revi System. The following tests were performed:

- Electrical bench testing including battery testing to support the performance and safety of the battery throughout its service life and stimulation (RF) characteristics to ensure accuracy with device specification.
- Mechanical bench testing including dimensional and tolerance analysis, and leg band performance.
- System performance bench testing to ensure system performance is in compliance with the technical specification.
- Transportation and storage per ASTM D4169 - Standard Practice for Performance Testing of Shipping Containers and Systems.
- Product stability to support the device durability and battery lifetime.
- Software verification to verify software requirements, including cybersecurity testing according to FDA Guidance documents titled "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
- Electrical safety per IEC 60601-1 Ed. 3.2 en: 2020.
- Electromagnetic Compatibility (EMC) testing per IEC 60601-1-2:2020 and IEC TS 60601-4-2 Edition 1.0 2024-03.
- Wireless Testing according to FDA Guidance document "Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and FDA Staff"

The test results demonstrate that the modified Revi System complies with its specifications and requirements and substantiate its equivalence to the cleared Revi System.

A human factors/usability evaluation of the Revi System with a comparative use-related risk analysis (URRA) found that no critical tasks were impacted or created by the subject device.

XII. Conclusion

The Revi System and its predicate device have the same intended use/indications for use and similar technological characteristics. The modifications introduced to the subject Revi System do not affect its principles of operation, underlying technology, essential mode of operation and principal functionality. The differences between the Revi System and its predicate do not present different questions of safety or effectiveness and the performance tests conducted on the subject device support the device is as safe and effective as the predicate. Therefore, the Revi System is substantially equivalent to the predicate device.