July 28, 2026

Bluewind Medical , Ltd.
% Elissa Burg
CEO / Regulatory Consultant
Biovision , Ltd.
Perach Halilach 183
Had-Nes, 1259000
Israel

Re: K253651
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 1, 2026
Received: July 1, 2026

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: 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANDREW M. FALES -S

for 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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253651

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

I. Submitter Information

Company: BlueWind Medical Ltd.
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Herzliya, 4614002
Israel

Contact: Elissa Burg
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BioVision Ltd.
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Date Prepared: July 23, 2026

II. Device name

Proprietary Trade Name:	Revi System
Common Name:	Implantable tibial electrical urinary continence device
Regulation Name:	Implanted tibial electrical urinary continence device (21 CFR 876.5305)
Classification:	Class II
Panel:	Gastroenterology/Urology
Product Code:	QXM

III. Predicate Device: Revi System (K240037)

IV. 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.

V. 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.

This 510(k) describes modifications to certain materials and manufacturing processes of the

Revi Implant as well as Implant lifetime extension to 15 years.

VI. Comparison of Technological Characteristics with Predicate

Description	Subject Device Revi System (K253651)	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 • HealthGo Micro Hub – communicates with the Wearable Unit to acquire data and transmit to the 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 • HealthGo Micro Hub – communicates with the Wearable Unit to acquire data and transmit to the Cloud
Principles of Operation	Implanted device receives power from non- implanted external Wearable Unit providing electrical stimulation to tibial nerve in proximity to ankle.	Implanted device receives power from non- implanted external Wearable Unit providing electrical stimulation to tibial nerve in proximity to ankle.
Energy Source	Wearable Unit powered by internal rechargeable battery.	Wearable Unit powered by internal rechargeable battery.
Intended Population	Adult Users	Adult Users
Use Environment	Rx only	Rx only
Main Implant Materials	Zirconia ceramic (BE grade)	Zirconia ceramic (B Grade)
Implant Labeled Lifetime	15 years	10 years

As evidenced by the above table, both the subject and the predicate devices have similar intended use, but the subject and predicate devices have different technological characteristics. Several performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate does not raise different questions of safety or effectiveness.

VII. Performance Testing

Below is a list of the tests that were performed and successfully completed for the subject

device per the following guidance and standards.

- Sterilization validation according to ISO 11135: Second edition 2014-07-15 - *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices* and FDA's Guidance: *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff (February 2024).*

- EO residual testing according to ISO 10993-7: Second edition 2008-10-15 - *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*

- Bacterial endotoxin testing according to ISO 11737-3: First Edition 2023-06 - *Sterilization of health care products – Microbiological methods – Part 3: Bacterial endotoxin testing*

- Bioburden estimation according to ISO 11737-1: Third edition 2018-01 [Including AMD1:2021] - *Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on product*

- Biocompatibility evaluation according to ISO 10993-1: Fifth edition 2018-08 - *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA Guidance: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* (September 8, 2023)

- Accelerated aging was performed according to ASTM F1980-21- *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

- Packaging integrity testing was performed according to ASTM F1886/F1886M-16 - *Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection,* ASTM F88/F88M-23 - *Standard Test Method for Seal Strength of Flexible Barrier Materials, and* ASTM F1929-15 - *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.*

Additionally, performance bench data was submitted for device performance and durability of the subject device. This data included:

- Electrical Functionality Testing
- Mechanical Enclosure Testing (Impact, Vibration, Shock, Axial Forces, and Pinching)
- Dimensional Validation Testing
- Corrosion Resistance Testing
- Ultrasound Compatibility Testing
- Active Aging Testing to Support 15-Year Implant Use-Life
- Particulate Matter Testing

- Pushout Force Testing
- Implant Overheating Testing
- Atmospheric Pressure Testing
- Operation Under Extreme Body Temperatures Testing

All pre-determined acceptance criteria were met.

VIII. Conclusion

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate.