March 12, 2026

Bionit Labs Srl
Aventaggiato Matteo
Co-Founder & COO
Via Cracovia 1
Soleto, LE 73010
Italy

Re: K260453
Trade/Device Name: Remote Wave Electrode (AE03-50); Remote Wave Electrode (AE03-60)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: February 11, 2026
Received: February 11, 2026

Dear Aventaggiato Matteo:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260453

Please provide the device trade name(s).

Remote Wave Electrode (AE03-50);
Remote Wave Electrode (AE03-60)

Please provide your Indications for Use below.

The Remote Wave Electrode is to be used exclusively for external prosthetic fittings of the upper limbs.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☒ Adolescents (12 years old to < 22 years old)
- ☒ Adults (22 years old and greater)

Special 510(k) Summary
Remote Wave Electrode

1. SUBMITTER INFORMATION

Manufacturer:	BionIT Labs Srl Via Cracovia 1 73010 – Soleto (LE) ITALY
Contact Person:	Matteo Aventaggiato
Contact Information:	m.aventaggiato@bionitlabs.com +39 393 4425 000
Date Prepared:	07/02/2025
Revision	First issue

2. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Remote Wave Electrode
Common/Usual Name:	Cutaneous electrode for External Upper Limb Prosthetic System
Model name	AE03-50 and AE03-60
Classification Name:	Cutaneous electrode
Regulation Number:	21 CFR 882.1320
Product Code:	GXY
Subsequent Product Code:	IQZ
Device Class:	Class II
Classification Panel:	Neurology

3. LEGALLY MARKETED PREDICATE DEVICE

510k number	Predicate Device	Device name	Manufacturer
K242326	I - Primary	Wave Electrode	BionIT Labs Srl

4. DEVICE DESCRIPTION

Remote Wave Electrode is an active analogue electrode for detecting any surface electromyographic signals, used for controlling prosthetic devices. It is compact and low-power, ensuring an accurate and fast reading of muscle electrical potentials generated voluntarily by the user. It also provides a real-time output signal proportional to the detected muscle activation.

Therefore,

Through the **Remote Wave Electrode** it is possible to non-invasively detect the electrical signal produced by the residual muscles on the patient's amputated limb (unilateral or bilateral amputees, starting from a transradial amputation level) and send an electrical signal to the electronic board of the prosthetic hand with a proportional width to the detected contraction.

Remote Wave Electrode is only compatible with the Adam's Hand Family, including Adam's Hand (medium e small), Adam's Hand Plus and Adam's Hook prosthetic hands that, according to the Regulation Number 890.3420, are classified as class I medical devices.

Remote Wave Electrode is available in two different models:

- Mod. AE03-50, with notch filter centred on the 50 Hz frequency;
- Mod. AE03-60, with notch filter centred on the 60 Hz frequency

5. INDICATION FOR USE

The **Remote Wave Electrode** is to be used exclusively for external prosthetic fittings of the upper limbs.

6. COMPARISON TO PREDICATE DEVICE

The following table compares the **Remote Wave Electrode** to the Wave Electrode, with pre-market authorization (K242326) approved, with respect to indications for use, principles of operation, technological characteristics, materials used, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or efficacy based on the similarities to the predicate devices.

Elements of Comparison	**Subject Device**	**Predicate Device**	Comparison Verdict
Manufacturer	BionIT Labs Srl	BionIT Labs Srl	
Trade Name	**Remote Wave Electrode**	Wave Electrode	
Models	AE03-50, AE03-60	AE02-50, AE02-60	
510(k) Number		K242326	-
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Classification Product Code	GXY	GXY	Same
Product device Classification	II	II	Same
Subsequent Product Code	IQZ	IQZ	Same
Intended Use / Indications for Use	The **Remote Wave Electrode** is to be used exclusively for	The Wave Electrode is to be used exclusively for external prosthetic	Same

	external prosthetic fittings of the upper limbs.	fittings of the upper limbs.	
Target group	The Remote Wave Electrode is suitable for unilateral or bilateral amputees. Adolescents (12 years old to < 22 years old) Adults (22 years old and greater)	The Wave Electrode is designed to be used by adults wearing mono- or bilateral amputations.	Similar: The Orthopedic Technician may prefer the Remote Wave Electrode in cases where the subject's or residual limb's anthropometric dimensions require it. The target group is the same as the predicate (K223738) used for the 510K of the Wave Electrode.
Principle of operation	Detect, process, and transmit physiological signals for use with a prosthesis and controls the terminal device.	Detect, process, and transmit physiological signals for use with a prosthesis and controls the terminal device.	Same
Environment of Use	Professional healthcare facility and home use	Professional healthcare facility and home use	Same
Assembling procedure	Components are assembled by a prosthetist	Components are assembled by a prosthetist	Same
Technological Characteristics - System			
Signal acquisition	EMG signals	EMG signals	Same
Output signal	The output is an analog signal with 0-5V dynamics, proportional to the instantaneous envelope of the EMG signal	The output is an analog signal with 0-5V dynamics, proportional to the instantaneous envelope of the EMG signal	Same
Principle of operation	Detect the EMG signal, process it, provide it as output to an electronic system that drives the opening/closing of a myoelectric prosthetic hand; this system can be integrated into the hand itself (as in the case of Adam's Hand)	Detect the EMG signal, process it, provide it as output to an electronic system that drives the opening/closing of a myoelectric prosthetic hand; this system can be integrated into the hand itself (as in the	Same

		case of Adam's Hand)	
Power Source	The **Remote Wave Electrode** does not require an additional battery beyond the one present in the upper limb prosthetic system.	The Wave Electrode does not require an additional battery beyond the one present in the upper limb prosthetic system.	Same
Power Requirements	6 - 8.4 V (DC) 2 mA	6 - 8.4 V (DC) 2 mA	Same
Software Control tools	No	No	Same
Terminal device (e.g., Hand, wrist, or elbow) included?	No	No	Same
Wireless Communication for electrode	No	No	Same
Technological Characteristics - Electrode			
Dimensions	27 x 18 x 7 mm	27 x 18 x 8 mm	Similar
Operating temperature	0°C - 40°C	0°C - 40°C	Same
Contact materials	AISI316L	ABS AISI316L	Similar In the case of the Remote Wave Electrode, only the steel AISI 316L domes are in contact with the skin.
Frequency bandwidth	90 - 450 Hz	90 - 450 Hz	Same
Safety and Performance Testing			
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
EMC Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	Same The contact material is the same approved with the predicate device

Given both Wave Electrode and the **Remote Wave Electrode** are intended to acquire the surface EMG signals, filter and amplify them analogically and input them to the electronics of the myoelectric prosthetic hand present in the prosthesis in which the electrodes are integrated, and acknowledging a few distinctions among the devices, it can be affirmed that the subject device is substantially equivalent to the predicate device.

The **Remote Wave Electrode** has the same characteristics as the Wave Electrode, but it has metallic plates for contact with the skin located outside the electrode case and connected to it through three shielded cables.

7. NON-CLINICAL PERFORMANCE DATA

Considering that the **Remote Wave Electrode** is intended to be used in conjunction with "Adam's Hand®" prosthetic hand, the safety of the electrodes have been demonstrated through the tests performed on the whole system (Electrodes + "Adam's Hand®" prosthetic hand)

- Electrical safety test according to IEC 60601-1 and IEC 60601-1-11 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard

The **Remote Wave Electrode** does not require an additional battery beyond the one present in the upper limb prosthetic system, and does not include any software.

The material used for the construction of the applied part of the Remote Wave Electrode (AISI 316L steel) is the same used for the cleared (K242326) Wave Electrode. The material has been directly evaluated for the biological safety to exclude the toxicological concerns, by an accredited laboratory as following:

- Cytotoxicity testing per ISO 10993-5
- Skin irritation testing per ISO 10993-10
- Sensitization testing per ISO 10993-23

The **Remote Wave Electrode** was also tested internally to ensure that it meets design specifications & requirements and operates as intended when is used in conjunction with "Adam's Hand®" prosthetic hand.

8. CLINICAL PERFORMANCE DATA

No human clinical testing was required to support the medical device as the indications for use are equivalent to the predicate device. These types of devices, belonging to product category GXY, have been on the market for many years with proven safety and efficacy for the use of the device. The nonclinical testing detailed in this submission supports the substantial equivalence of the device.

9. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The technological characteristics, features, specifications, materials, mode of operation, and intended use of **Remote Wave Electrode** are substantially equivalent to the electrodes included in the Wave Electrode quoted above.already placed on the US market K242326.