January 2, 2025

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

Re: K242326
Trade/Device Name: Wave Electrode (AE02-60); Wave Electrode (AE02-50)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: July 30, 2024
Received: August 6, 2024

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 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and Rehabilitation Devices
OHT5: Office of Neurological and Physical Medicine 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)*

K242326

Device Name

Wave Electrode (AE02-60);
Wave Electrode (AE02-50)

Indications for Use *(Describe)*

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

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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Traditional 510(k) Summary
Wave Electrode - K242326

1. SUBMITTER INFORMATION

Manufacturer: BionIT Labs Srl
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73010 – Soleto (LE)
ITALY

Contact Person: Matteo Aventaggiato

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Date Prepared: 02/01/2025

Revision 4

2. DEVICE IDENTIFICATION

Trade/Proprietary Name:	Wave Electrode
Common/Usual Name:	Cutaneous electrode for External Upper Limb Prosthetic System
Model name	AE02-50 and AE02-60
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
K220002	I - Primary	Dexus Prosthetics System	Zhejiang Qiangnao Technology Co.,Ltd
K223738	II - Secondary	Alpha Control Liner System (ACLS)	Coapt, LLC

4. DEVICE DESCRIPTION

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 **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.

Wave Electrode is only compatible with the Adam's Hand prosthetic hand that, according to the Regulation Number 890.3420, are classified as class I medical device.

Wave Electrode is available in two different models:

- Mod. AE02-50, with notch filter centred on the 50 Hz frequency;
- Mod. AE02-60, with notch filter centred on the 60 Hz frequency

5. INDICATION FOR USE

The **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 **Wave Electrode** to the predicate devices 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 I**	**Predicate Device II**	Comparison Verdict
Manufacturer	BionIT Labs Srl	Zhejiang Qiangnao Technology Co.,Ltd	Coapt, LLC Contract Manufacturer: WillowWood Global LLC	
Trade Name	**Wave Electrode**	Dexus Prosthetic System	Alpha Control Liner System	
Models	AE02-50, AE02-60	MSL1, MSR1	-	
510(k) Number	K242326	K220002	K223738	-
Classification Name	Cutaneous electrode	Cutaneous electrode	Cutaneous electrode	same
Classification Product Code	GXY	GXY	GXY	same
Product device Classification	II	II	II	same
Subsequent Product Code	IQZ	IQZ	IQZ	same
Intended Use / Indications	The **Wave Electrode** is to be used	The Dexus Prosthetic System is	The Alpha Control Liner System is to be used	same

for Use	exclusively for external prosthetic fittings of the upper limbs.	to be used exclusively for external prosthetic fittings of the upper limbs.	exclusively for exoprosthetic fittings of the upper limbs.	
Target group	The Wave Electrode is designed to be used by ADULTS wearing mono- or bilateral amputations.	Dexus Prosthetic System is suitable for upper limb disabled groups for upper limb amputees.	The Alpha Control Liner System is suitable for unilateral or bilateral amputations.	same
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.	The Alpha Control Liner System is an interface solution designed to provide the Complete Control System Gen2with amputee muscle contraction signals needed for the pattern recognition algorithms.	same
Environment of Use	Professional healthcare facility and home 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	The components of the Alpha Control Liner System are assembled by a prosthetist according to the individual needs of the amputee.	same
Technological Characteristics - System				
Signal acquisition	EMG signals	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 of the EMG signal	The output is an analog and or digital signal of the EMG signal	Same of predicate I Negligible differences for predicate II
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 case of Dexus prosthetic 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 external as in the case by Coapt Gen 2.	Same of predicate I Negligible differences for predicate II
Power Source	The **Wave Electrode** does not require an additional battery beyond the one	Rechargeable battery (included in the system)	The Alpha Control System is used in conjunction with the Coapt Complete Control System Gen2	same

	present in the upper limb prosthetic system.		and does not require an additional battery.	
Power Requirements	6 - 8.4 V (DC) 2 mA	-	5.3–16.8 VDC 115 mA at 7.4 V	Similar (1) The range of the subject device is included in the predicate device II
Software Control tools	No	Yes	Yes Complete Control Room Software	Different (2) The subject device does not use any software tool to control the signal.
Terminal device (e.g., Hand, wrist, or elbow) included?	No	Yes	No	Similar/same (3) The subject device does not include prosthetic limbs as the predicate II device.
Wireless Communication for electrode	No	No	No	Same
Technological Characteristics - Electrode				
Dimensions	27 x 18 x 8 mm	34.5 x 16 x 11.5 mm	-	Similar (1)
Operating temperature	0°C - 40°C	0°C - 40°C	-	Same of the predicate I device.
Contact materials	ABS AISI316L	Polycarbonate: PC2858, Thermoplastic Elastomer: TM5ADT and Metal Pieces (Copper gold plated): C1SQIN	Electrodes: Stainless Steel 316L Liner: Tri-block copolymer gel	Similar (4) Additional Biocompatibility testing performed
Frequency bandwidth	90 - 450 Hz	80 - 500 Hz	-	Similar (1) The range of the subject device is included in the predicate device I
Safety and Performance Testing				
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	IEC 60601-1	same
EMC Compatibility	IEC 60601-1-2	IEC 60601-1-2	-	Same
Biocompatibility	ISO 10993-1	ISO 10993-1	ISO 10993-1	Same (5)

	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	The subject device has been tested according to the state of art of the biocompatibility standard.

Given that the **Wave Electrode** is 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 devices.

(1) Although the **power requirements, dimensions, and frequency bandwidth** of the subject device are slightly different from the predicate devices, all of them meet the requirements of safety and performance standards IEC 60601-1. So, the differences between the predicate devices and the subject device will not affect the safety and effectiveness of the subject device.

(2) The subject device communicates directly with the upper limb prosthetic systems.
Wave Electrode is an analog device and has no on-board programmable electronics (FW and or PEMS).
The subject device cannot lead to risks resulting from programmable electronics malfunctioning than the predicates .

(3) The subject device does not include prosthetic limbs.
Performance tests have showcased the compatibility of the Wave Electrode with only Adam's Hand prosthetic limb that can be utilized in conjunction with it.

(4) Although the **contact materials** of the subject device are different from the predicate devices, all the materials that in NORMAL USE come into contact to the PATIENT meet the requirements of ISO 10993 series standards. So, the differences between the predicate device and the subject devices will not affect the safety and effectiveness of the subject device.

(5) Although the subject device, the predicate device I (primary), and the predicate device II (secondary) use slightly different versions of the test standards, the subject device is in compliance with the state of art standards. So, the differences between the predicate devices and the subject device will not affect the safety and effectiveness of the subject device. The ISO **10993- 23** specifies the procedure for the assessment of medical devices and their constituent materials with regard to their potential to produce irritation, this specifies was included in the ISO **10993- 10**.

7. NON-CLINICAL PERFORMANCE DATA

Considering that the **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 **Wave Electrode** does not require an additional battery beyond the one present in the upper limb prosthetic system, and not included any software.

Wave Electrode 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 **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 is equivalent to the predicate device. These types of devices, including the predicate device, 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 **Wave Electrode** are substantially equivalent to the electrodes included in the **Dexus Prosthetics System** and the electrode **Alpha Control Liner System (ACLS)** quoted above.

The differences between the subject device and primary predicate device do not raise new issues of safety or effectiveness. Thus, the subject device is substantially equivalent to the already placed on the US market primary predicate device K220002.