September 27, 2019

Otto Bock Healthcare Products GmbH
℅ Rene Urtz
Regulatory Affairs Manager
Otto Bock Healthcare Products GmbH
Brehmstrabe 16 1110 Wien
Vienna, AT

Re: K191179
Trade/Device Name: Myo Plus
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: August 6, 2019
Received: August 9, 2019

Dear Rene Urtz:

This letter corrects our substantially equivalent letter of September 4, 2019.

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 (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 located 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.

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

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

Heather L. Dean -S

For: Vivek Pinto, Ph.D.
Acting Division Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191179

Device Name
Myo Plus

Indications for Use *(Describe)*
Myo Plus is to be used exclusively for exoprosthetic 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.

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

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510(K) SUMMARY

1 Submitter Information

510(k) owner:	Otto Bock Healthcare Products GmbH
Establishment Registration:	3005190268
Address:	Brehmstraße 16 1110 Vienna Austria
Contact Person:	Rene Urtz Regulatory Affairs Manager rene.urtz@ottobock.com
Telephone:	+43 1 523 37 86 707
Fax Number:	+43 1 523 22 64
Date Prepared:	September 03, 2019

2 Device Information

Trade Name:	Myo Plus
Common or Usual Name:	Powered, External Upper Limb Prosthetic System
Classification Name:	Cutaneous Electrode (21 CFR 882.1320)
Classification Product Code:	GXY (Electrode, Cutaneous)
Subsequent Product Code:	IQZ (Hand, External Limb Component, Powered)

3 Predicate Devices

510(k) Number:	K182112
Device Name:	Sense System with IBT Electrodes

4 Indications for Use

Myo Plus is to be used exclusively for exoprosthetic fittings of the upper limbs.

5 Device Description

MYO PLUS measures the electromyographic control signals of the user and assigns them to the movements of the prosthesis, such as the hand or rotation unit. The product is the central control unit of a myoelectric prosthesis. By calibrating via the Myo Plus App, the control unit learns to assign muscle signals from the user to the various types of movement. This calibration can be performed by the users themselves, and repeated at regular intervals if necessary.

Description of the components:

Myo Plus TR
The central control unit is installed in the forearm of the prosthesis and is supplied with energy by the battery system of the prosthesis. Up to 8 remote electrodes can be connected. The electronics handles the signal processing of the electrode signals and controls the compatible prosthesis components.

Remote Electrode
The remote electrodes take the muscle signal from the skin surface and transmit it to MyoPlus TR. The electrode contacts are located on a flexible cable and are individually screwed into the socket by the prosthesist.

Myo Plus App
The Myo Plus App is the central interface for the user and/or professionals to make settings on the control system or monitor operating states. The data transfer to mobile setting systems on Android or mobile iOS devices shall be carried out by a wireless connection according to the state of the art.

Myo Cuff
The Myo Cuff is used to evaluate the muscle signals of a potential user of a Myo Plus controller. The Myo Cuff forms a flexible wristband which is temporarily applied to the user's forearm. Thus, the signal patterns of the user can be evaluated with the help of the app without the preparation of a complex test socket. If a user has problems separating the patterns at the beginning, he can also use the Myo Cuff for practicing with an professional.

Myo Plus trial kit
The Myo Plus trial kit provides the components of Myo Plus as a loaner kit for the prosthesist.

6 Substantial Equivalence

The following table compares Myo Plus to the predicate device with respect to indications for use, principle of operation, technological characteristics and safety and performance testing.

	Myo Plus	Predicate device	Comparison
510k number	To be determined	K182112	-
Device name, Model	Myo Plus	Sense System with IBT Electrodes	-
Manufacturer	Otto Bock HealthCare Products GmbH	Infinite Biomedical Technologies, LLC	-
Classification, Indications for Use and Intended Use			
Classification Product Code	GXY	GXY	Same
Subsequent Product Code	IQZ	IQZ	Same
Indications for Use	Myo Plus is to be used exclusively for exoprosthetic fittings of the upper limbs.	Sense System with IBT Electrodes is to be used exclusively for external prosthetic fittings of upper limbs.	Same
Principle of operation	Detect, process, and transmit physiological signals for use with a prosthesis.	Detect, process, and transmit physiological signals for use with a prosthesis.	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 electrode	EMG electrode	Same
Adjustment software	Yes Myo Plus App	Yes User Interface Application	Same
Software/Firmware/Micro processor Control?	Yes	Yes	Same
Input voltage	5,5-12 VDC	5 to 10 VDC (system)	Similar
Output signal	0 – 4,5V digital and 0-8.2V motor (analog)	0-3.3V digital and 0-7.4V motor	Similar
Terminal device (e.g. hand, wrist or elbow) included?	No	No	Same
Wireless Communication	Yes Bluetooth	Yes Bluetooth	Same
Component for training and capabilities assessment	Yes Myo Cuff	No	Differs
Power source included?	Included in component MyoCuff	No	Differs
Technological Characteristics - Processing unit			
Dimensions	67 x 27 x 9.2 mm	59 x 27.8 x 9.8 mm	Similar
Control Options	Pattern recognition, State switching	Pattern recognition	Similar
Input Button	None	None	Same

Technological Characteristics - Electrode			
Dimensions	40.8 x 13.8 x 5.3 mm	28.8 x 16.8 x 6.7mm	Similar
Temperature range (use)	+5°C to +40°C (41°F to 104°F)	-10°C to +50°C (14°F to 122°F)	Similar
Housing material	TECHNOMELT PA 638 BLACK Polyamid	Plastics(ABS/PC Blend) Polycarbonate/Acrylnitril Butadien Styrol	Differs
Contact area	Titanium (grade 2)	Titanium (grade 1)	Similar
Signal processing	Digital	Digital	Same
Frequency bandwidth	80 - 500 Hz	90-500Hz	Similar
Adjustment	none	Digital gain 1-7	Differs
Installation	Suspension arms/suction socket	Suspension arms/suction socket	Same
Safety and Performance Testing			
Electrical Safety	IEC 60601-1:2005/A1:2012 IEC 60601-1-11:2015	IEC 60601-1:2005/A1:2012 IEC 60601-1-11:2010	Similar
Electromagnetic Compatibility	IEC 60601-1-2:2012	IEC 60601-1-2:2007	Similar
Biocompatibility	ISO 10993-1:2009	ISO 10993-1:2009	Same
Battery Safety	IEC 62133-2:2017 ST/SG/AC.10/11/Rev.5/ Amend.2, Sub-section 38.3	IEC 62133:2002 ST/SG/AC.10/11/Rev.5/ Amend.2, Sub-section 38.3	Similar

The following table shows a brief summary of additional non-clinical performance testing conducted to support substantial equivalence.

Test	**Result**
Functional testing	Passed
Adaptation to the user through calibration	Passed
Commissioning by user	Passed
Pattern recognition	Passed
Wireless data transmission	Passed
Product compatibility	Passed
Product lifetime	Passed
Battery life	Passed

Myo Plus passed all the safety and performance testing in accordance with internal requirements and international standards, including those shown herein to demonstrate its ability to achieve its intended use and to support the substantial equivalence.

7 Conclusions

Myo Plus has the same indications for use, the same principle of operation and similar technological characteristics as the predicated device cleared under 510(k) no. K182112.

Based on the supporting data and the discussion provided herein, Otto Bock Healthcare GmbH considers its Myo Plus to be substantially equivalent to the predicate device.