April 22, 2026

Otto Bock Healthcare Products GmbH
Rene Urtz
Regulatory Affairs Manager
Brehmstrasse 16
Vienna, 1110
Austria

Re: K253256
Trade/Device Name: myosmart. (13E522);
myosmart.cuff (757M20-2, 757M20-2=50, 757M20-2=60);
connectgrip. (560X27-1, 560X27-1=IOS, 560X27-1=ANDR);
myosmart trial kit (642V64=T)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: September 26, 2025
Received: September 29, 2025

Dear Rene Urtz:

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,

FDA
Digitally signed by ZACHARY MCKINNEY -S
Date: 2026.04.22 00:28:47 -04'00'

for Tushar Bansal, PhD
Acting Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253256

Device Name
myosmart. (13E522); myosmart.cuff (757M20-2, 757M20-2=50, 757M20-2=60);
connectgrip. (560X27-1, 560X27-1=IOS, 560X27-1=ANDR); myosmart trial kit (642V64=T)

Indications for Use *(Describe)*
Myosmart 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.

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K253256 510(k) Summary

1 Submitter´s Information

Name/Manufacturer	Otto Bock Healthcare Products GmbH
Address	Brehmstrasse 16, Vienna, AT-1110, Austria
Phone Number	+4315233786676
E-Mail	reinhard.wolkerstorfer@ottobock.com
Contact Person	Reinhard Wolkerstorfer
Date Prepared	April 16, 2026

2 Correspondent Contact

Contact Person	Rene Urtz
Company	Otto Bock Healthcare Products GmbH
Phone Number	+4315233786707
E-Mail	rene.urtz@ottobock.com

3 Device Information

Trade Name	myosmart. (13E522);
	myosmart.cuff (757M20-2, 757M20-2=50, 757M20-2=60);
	connectgrip. (560X27-1, 560X27-1=IOS, 560X27-1=ANDR);
	myosmart trial kit (642V64=T)

Common Name	Powered, External Upper Limb Prosthetic System
Classification Name	Electrode, Cutaneous
Classification Product Code	GXY, IQZ
Regulation Number	882.1320

4 Primary Predicate Device Information

Device Name	Myo Plus
Common Name	Powered, External Upper Limb Prosthetic System
Device Manufacturer	Otto Bock Healthcare Products GmbH
Classification Name	Cutaneous Electrode
Classification Product Code	GXY, IQZ
Regulation Number	882.1320
510(k) Number	K191179

5 Secondary Predicate Device Information

Device Name	Glide (91000-GL-X)
Common Name	Powered, External Upper Limb Prosthetic System
Device Manufacturer	Infinite Biomedical Technologies, LLC
Classification Name	Cutaneous Electrode
Classification Product Code	GXY, IQZ
Regulation Number	882.1320
510(k) Number	K240884

6 Indications for Use Statement

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

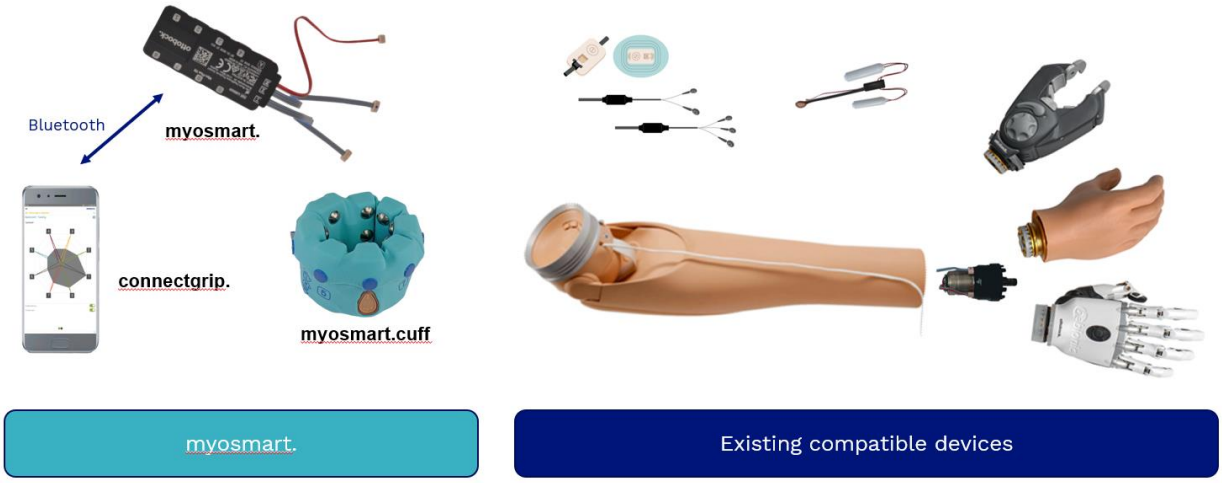
7 Device Description

The myosmart is to be used exclusively for exoprosthetic fittings of the upper limbs.
The myosmart (article no. 13E522-1) is a myoelectric control that provides personalized and precise control of prosthetic components and caters to individual user needs, such as assigning movements of the prosthesis to the hand or rotation unit. It is suitable for controlling myoelectric prosthesis, offers personalized and adaptive control for seamless movement and is using advanced signal processing for muscle signal detection and can be calibrated by the users themselves, and repeated at regular intervals if necessary.

The myosmart cuff (article no. 757M20-2*) is a flexible armband that is temporarily applied to the user's forearm or upper arm.

It makes it possible to evaluate the user's muscle signals and patterns using the myosmart connectgrip app (article no. 560X27-1*), without fabricating a check socket.

The myosmart trial kit (642V64=T*) provides the components of myosmart as a loaner kit for the prosthesist.



8 Functional Principles

Myoelectrically controlled arm prostheses are externally powered devices that use electromechanical components supplied with electrical energy from a battery. These prostheses are operated through intentional muscle contractions in the residual limb, where prosthetic movements are initiated by muscle activity known as myoelectric signals (myo signals). These signals are detected using electromyography (EMG), a technique for measuring muscle activity.

Following a traumatic amputation, the remaining muscles in the residual limb remain functional and can still be activated when imagining phantom hand movements. Individuals with congenital limb differences can generate myo signals using their existing muscles. Myo signals from the residual limb muscles can be accurately measured and utilized for prosthesis control.

In myoelectric prosthetics, surface electrodes are employed to capture myo signals. These electrodes are non-invasive and placed on the skin's surface. The myosmart system leverages these signals to facilitate intuitive prosthesis control. The myosmart microprocessor control unit learns and stores an individual's unique myo signals, enabling a seamless and user-specific control experience.

9 Substantial Equivalence Discussion

Description/ Parameter	Subject Device (myosmart)	Primary Predicate device (K191179) [Predicate Device 1]	Secondary Predicate Device (K240884) [Predicate Device 2]	Evaluation
System				
Intended Use	myosmart is to be used exclusively for exoprosthetic fittings of the upper limbs.	Myo Plus is to be used exclusively for exoprosthetic fittings of the upper limbs.	Glide is to be used exclusively for exoprosthetic fittings of the upper limbs.	Same
Power Source included?	Included in myosmart.cuff	Included in component MyoCuff	No	Same in predicate device 1 Different than predicate device 2, as it does not have a built-in battery, but it is intended to be „compatible with multiple prosthetic powering systems". Since the battery is tested according to safety standards, the difference does not raise new safety or effectiveness concerns.
Terminal device (hand, wrist or elbow) included?	No	No	No	Same
Wireless communication	Bluetooth®, 5.0	Bluetooth®, 4.0	Bluetooth®	Same standard (Bluetooth) as used in the predicate devices; just a newer version.
Clinical Software Tool	Yes connectgrip	Yes Myo Plus App	Yes IBT Control Application	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same
Power Input Voltage	6 – 8.2 VDC	6 V–11.1 V DC	5-10 V DC	Similar to predicate device 1 it operates in the same voltage range but with a lower max. voltage. This reflects a design optimization and does not raise new safety or effectiveness concerns – Lower maximum Voltage = less risk) Different than predicate device 2, it offers a wider power input voltage range as it is „compatible with multiple prosthetic powering systems". The narrower input range of myosmart is suitable for its compatible batteries. The difference does not raise new safety or effectiveness concerns.

Description/ Parameter	Subject Device (myosmart)	Primary Predicate device (K191179) [Predicate Device 1]	Secondary Predicate Device (K240884) [Predicate Device 2]	Evaluation
System				
Output Signal	Analog and digital	Analog and Digital	Analog and Digital	Same
Control Unit				
Processing Unit (L x W x H)	67 x 27 x 9.2 mm	67 x 27 x 9.2 mm	Core2 Controller 59 x 27.8 x 9.8mm	Same as predicate device 1 Different from predicate device 2(non-ublic information)
Weight	15g	15g	10g	Same as predicate device 1 Different from predicate device 2, however the increased weight (15g vs. 10g) is minimal and does not affect the device's wearability, safety, or intended use.
Pattern recognition	Yes (Directly assigned movements and joint change detection)	Yes (Directly assigned movements)	Unknown	Similar to predicate device 1. Change detection expands user fitting options. Different from predicate device 2 (non-public information) The difference does not raise new safety or effectiveness concerns.
Control options	Multiple	Multiple	Multiple	Same
Electrodes				
Electrode (L x W x H)	a) Electrode (cleared within K123795) 27x18x9,5 b) Remote Electrode (cleared within K191179) 40.8 x 13.8 x 5.3 mm	Remote Electrode (cleared within K191179) 40.8 x 13.8 x 5.3 mm	IBT Electrode 26.8 x 14.8 x 7.5mm	Both compatible Electrodes are already cleared under K123795 and K191179
Temperature range (use)	a) -15°C to 60°C b) +5°C to +40°C	+5°C to +40°C	-10° to 60°C	
Type	a) Cased b) Remote	Remote	Remote	
Housing Material	a) Acrylonitrile styrene acrylate b) Polyamide	Polyamide	Nylon12 (PA12)	
Contact Area	a) Titanium (grade 1) b) Titanium (grade 2)	Titanium (grade 2)	No skin contacting part Compatible with industry standard domes	
Number	2 to 4	3 to 8	2 to 8	
Bonding Agent	Cyanoacrylate	Cyanoacrylate	Cyanoacrylate	
Signal processing	a) Analog b) Digital	Digital	Digital	
Frequency Bandwidth	a) 90 – 450 Hz b) 80 – 500 Hz	80 – 500 Hz	90 - 300 Hz	
Adjustment	a) Analog Gain 1 – 7 b) none	none	Digital Gain 1-10	
Installation	Suspension arms / suction socket	Suspension arms / suction socket	Suspension arms / suction socket	
Safety and Performance Testing				
Electrical Safety	IEC60601-1:2005+AMD1:2012+AMD2:2020 IEC60601-1-11:2015+AMD1:2020	IEC 60601-1:2005/A1:2012 IEC 60601-1-11:2015	IEC60601-1:2005+AMD1:2012+AMD2:2020 IEC60601-1-11:2015+AMD1:2020	Same recognized consensus standard(s) as predicate devices
Electromagnetic Compatibility	IEC 60601-1-2:2014+AMD1:2020	IEC 60601-1-2:2012	EN 60601-1 2:2015+A1:2021	Same recognized consensus standard(s) as predicate devices
Biocompatibility	ISO 10993-1:2018	ISO 10993-1:2009	Unknown	Same recognized consensus standard(s) as predicate devices

Description/ Parameter	Subject Device (myosmart)	Primary Predicate device (K191179) [Predicate Device 1]	Secondary Predicate Device (K240884) [Predicate Device 2]	Evaluation
System				
Battery Safety	IEC 62133-2:2017 ST/SG/AC.10/11/Rev.5/ Amend.2, Sub-section 38.3	IEC 62133-2:2017 ST/SG/AC.10/11/Rev.5/ Amend.2, Sub-section 38.3	Not applicable	Same recognized consensus standard(s) as predicate devices

The results of the completed evaluations and testing demonstrate that any differences do not raise different questions of safety and effectiveness, and the performance data demonstrate acceptable safety and performance compared to the predicate devices.

10 Performance Data

The electrodes used were previously cleared under their respective 510(k)´s K123795 and K191179.

The nonclinical testing conducted to support substantial equivalence for the myosmart., myosmart.cuff, connectgrip, and myosmart trial kit includes verification and validation activities aligned with FDA-recognized consensus standards and applicable guidance documents. These tests address risk management, usability, software lifecycle, electrical safety, electromagnetic compatibility, battery safety, wireless communication, biocompatibility, and labeling.

The device has met all applicable requirements for:

- ISO 14971:2019 - Risk management
- IEC 62366-1:2015+A1:2020 - Usability engineering
- IEC 62304:2006+A1:2015 - Software lifecycle
- IEC 60601-1:2005+A1:2012+A2:2020 and related collateral standards - Electrical safety and EMC
- IEC 62133-2:2017 - Battery safety
- ISO 10993-1:2018 - Biocompatibility
- ISO 20417:2021 and ISO 15223-1:2021 - Labeling and symbols

Verification and validation testing was conducted to demonstrate the pattern recognition and machine learning features of the device were as safe and effective as the predicate device

All test results were within acceptable limits and no new safety or effectiveness concerns were identified.

11 Conclusion

The myosmart system has the same intended use as the predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the performance data demonstrate that the myosmart system is substantially equivalent to the cleared predicate devices.