September 9, 2022

Zhejiang Qiangnao Technology Co.,Ltd
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K220002
Trade/Device Name: Dexus Prosthetics System (Model: MSL1, MSR1)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: June 8, 2022
Received: June 13, 2022

Dear Cassie Lee:

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,

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

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)*
K220002

Device Name
Dexus Prosthetics System (Model: MSL1, MSR1)

Indications for Use *(Describe)*
The Dexus Prosthetic System 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.

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510(k) Summary for K220002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

1. Submitter's Information

510(k) Owner's Name: Zhejiang Qiangnao Technology Co.,Ltd
Establishment Registration Number: Applying
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Tel: +86 20 8266 2446
E-mail: regulatory@share-info.com

Date of the summary prepared: 8/19/2022

2. Subject Device Information

Type of 510(k): Traditional
Common Name: Powered, External Upper Limb Prosthetic System
Classification Name: Cutaneous electrode
Trade Name: Dexus Prosthetics System
Model Name: MSL1, MSR1
Review Panel: Neurology
Product Code: GXY, IQZ
Regulation Number: 21 CFR 882.1320
Regulatory Class: II

3. Predicate Device Information

Sponsor: Otto Bock Healthcare Products GmbH
Trade Name: Axon-Bus Prosthetic System
Common Name: Powered, External Upper Limb Prosthetic System

Classification Name: Cutaneous Electrode
510(K) Number: K123795
Review Panel: Neurology
Product Code: GXY, IQZ
Regulation Number: 21 CFR 882.1320
Regulation Class: II

4. Device Description

The Dexus Prosthetic System is to be used exclusively for external prosthetic fittings of the upper limbs. This Dexus Prosthetic System is suitable for upper limb disabled groups (wrist disarticulated, forearm amputated, congenital missing hand, etc.), for upper limb amputees to compensate or make up for some of the functions of the amputated limb. It applies the surface electromyography (sEMG) signal to realize the control of the upper limb prosthetic device. The collected EMG signals are processed through specific algorithms to achieve the delicate control of the prosthetic hand. The Dexus Prosthetic System is developed to facilitate daily life and must not be used for unusual activities (e.g. sports that may damage the mechanical wrist, like pushups) and should not be used for the operation of motor vehicles, heavy equipment, industrial machines, or motor-driven equipment.

The Dexus Prosthetic System is not suitable for patients with severe disorders of blood clotting mechanism, patients with mental diseases, patients with unhealed wound on the stump, and other patients who are considered medically unable to fit a prosthetic hand.

The Dexus Prosthetic System is intended exclusively for use on one patient. The Dexus Prosthetics System needs to be installed by trained prosthetists to meet the needs of the end-users.

The Dexus Prosthetic system consists of an electric prosthetic hand and a socket (customized according to the stump of the user and does not come with the subject device), two electrodes, electrode patch cord and electrode screw, charging cord, battery, battery cable and adapter plate, heat-shrinkable sleeve, Power switch assembly, some screws and glove.

The Dexus Prosthetic System has a total of 6 degrees of freedom (DOF), the distribution is as follows:

- Thumb (1st finger) DOF: 2 degrees of freedom, which are flexion/extension, adduction/abduction, respectively, a combination of them can make the thumb move freely, and the state can be identified;
- Index finger (2nd finger) DOF: 1 degree of freedom, flexion/extension movement;
- Middle finger (3rd finger) DOF: 1 degree of freedom, flexion/extension movement;
- Ring finger (the 4th finger) DOF: 1 degree of freedom, flexion/extension movement;
- Little finger (5th finger) DOF: 1 degree of freedom, flexion/extension movement.

In addition, its gesture functions include Prehensile Grasp, Tipping, Tripod Pinch, Index pointing, Lateral Pinch, and Hook. The functions can be switched through the buttons on the back of the

hand.

5. Intended Use / Indications for Use

The Dexus Prosthetic System is to be used exclusively for external prosthetic fittings of the upper limbs.

6. Test Summary

6.1 Summary of Non-Clinical Tests

Dexus Prosthetics System has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-1-11 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Safety test of lithium battery according to IEC 62133-2 standard
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

6.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Dexus Prosthetics System is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Zhejiang Qiangnao Technology Co.,Ltd	Otto Bock Healthcare Products GmbH	--
Trade Name	Dexus Prosthetic System	Axon-Bus Prosthetic System	--
Models	MSL1, MSR1	--	--
510(k) Number	K220002	K123795	--
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Classification Product Code	GXY	GXY	Same
Subsequent Product Code	IQZ	IQZ	Same
Intended Use / Indications for Use	The Dexus Prosthetic System is to be used	The Axon-Bus Prosthetic System is to be used	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
	exclusively for external prosthetic fittings of the upper limbs.	exclusively for exoprosthetic fittings of the upper limbs.	
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
System Components	Dexus Hand (terminal device) Dexus Wrist (passive rotation) Dexus Power (battery) Dexus Charge (charger) Dexus Center (control unit) Dexus Electrode (detect EMG signals) Dexus Skin (prosthetic glove)	Michelangelo Hand (terminal device) AxonFlexion Adapter (passive flexion) AxonRotation Adapter (passive rotation) AxonArm (passive elbow joint with mechanical and/or electrical lock) AxonEnergy Integral (battery) AxonCharge (charger) AxonMaster (control unit) Electrode (detecting EMG Input signals) AxonSoft (adjustment software) AxonSkin (prosthetic glove)	Similar Note 1
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
Power Source	Rechargeable battery	Rechargeable battery	Same
Adjustment software	No	Yes AxonSoft	Different Note 2
Software/Firmware/Micropr	Yes	Yes	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
ocessor Control?			
Terminal device (e.g., Hand, wrist or elbow) included?	Yes	Yes	Same
Wireless Communication	No	Yes Bluetooth	Different Note 2
Technological Characteristics - Hand			
Operating temperature	+5°C to +40°C	-10°C to +60°C	Different Note 3
Weight	530g	600g (incl. Passive flexion and rotation)	Different Note 3
Max. Gripping force	70N (opposition mode) 60N (lateral mode) 15N (neutral mode)	70N (opposition mode) 60N (lateral mode) 15N (neutral mode)	Same
Max. Grip Speed	150mm/s	325mm/s	Different Note 4
Max. Opening Width	106mm	120mm	Different Note 3
Technological Characteristics - Electrode			
Dimensions	34.5mm x 16mm x 11.5mm	27mm x 18mm x 9.5mm	Different Note 3
Operating temperature	0°C - 40°C	-15°C to +60°C	Similar Note 3
Material	Polycarbonate: PC2858, Thermoplastic Elastomer: TM5ADT and Metal Pieces (Copper gold plated): C1SQIN	Piastics (ASA) Silicone Cyanacrylate	Different Note 5
Contact area	Copper gold plated	Titanium (grade 1)	Different Note 5
Frequency bandwidth	80 - 500 Hz	90 - 450 Hz	Similar Note 4
Adjustment	None	Potentiometer 1-7	Different Note 3
Installation	Suction socket	Suspension arms/suction socket	Same
Technological Characteristics - Battery			
Chemistry	Li Ion	Li Ion	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Number of cells	2	3	Different Note 6
Nominal voltage	7.4V	11.1V	Different Note 6
Battery capacity	2200mAh	Various (1150mAh/1500mAh)	Different Note 6
Charging time	Max.3.0h	Max.3.5h	Different Note 6
Battery weight	110g	140g	Different Note 3
Battery dimensions (L*W*H) (mm)	68x38x20	various (75x60x21 / 55x35x23)	Different Note 3
Installation	Integrated	Integrated	Same
Safety and Performance Testing			
Electrical Safety	IEC 60601-1:2005/A1:2012 IEC 60601-1-11:2015	IEC 60601-1:2005	Similar Note 7
Electromagnetic Compatibility	IEC 60601-1-2:2014	IEC 60601-1-2:2007	Similar Note 7
Biocompatibility	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993:2009	Same

Comparison in Detail(s):

Note 1:

Although the “System Components” of the subject device is different from the predicate device, the difference is that the subject device does not have related components and adjustment software for the elbow joint part. Because the subject device is only suitable for users with residual limbs of the elbow and forearm, not for users with deformed elbow joints, so the subject device is no related components for the elbow joint part. And the adjustment software is for the subsequent adjustment of the assembly posture, but the theme device will adjust the preset posture for the user before assembly. So, the difference will not affect the safety and effectiveness of the subject device.

Note 2:

The “Adjustment software” and “Wireless Communication” of the subject device are different from the predicate device, although there is no adjustment software, wireless function or control method, it is already adjusted in the product when the subject device preset, which will not affect any daily

usage. So, the slight difference will not affect the safety and effectiveness of the subject device.

Note 3:

Although the “Operating temperature”, “Dimensions”, “Max. Opening Width”, and “Adjustment” of the subject device are different from the predicate device, all of them meet the requirements of safety and performance standards IEC 60601-1. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

Note 4:

Although the “Max. Grip Speed” and “Frequency bandwidth” of the subject device are different from the predicate device, all of them meet the requirements of performance requirements. The differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

Note 5:

Although the “Material” and “Contact area” of the subject device are different from the predicate device, all the materials intended to be contacted by the patients of them meet the requirements of ISO 10993 series standards. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

Note 6:

Although the “Operating temperature”, “Dimensions”, “Max. Opening Width”, and “Adjustment” of the subject device are different from the predicate device, all of them meet the requirements of safety and performance standards IEC 60601-1. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

Note 7:

Although the subject device and the predicate device use slightly different versions of the test standards, the subject device is in compliance with the currently valid standards. So, the differences between the predicate device and the subject device will not affect the safety and effectiveness of the subject device.

8. Final Conclusion:

The subject device Dexus Prosthetics System has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device K123795.