August 27, 2026

Zhejiang Qiangnao Technology Co.,Ltd
℅ Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant , Ltd.
1919-1920, Bldg. D3, Minjie Plz., Shuixi Rd.,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K262654
Trade/Device Name: Dexus Prosthetic System (MSL2, MSR2)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: July 29, 2026
Received: July 30, 2026

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 (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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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

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.	K262654

Please provide the device trade name(s).

Dexus Prosthetic System (MSL2, MSR2)

Please provide your Indications for Use below.

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

Please select the types of uses.

- [x] 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)
- [x] Adults (22 years old and greater)

510(k) Summary
K262654

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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Application Correspondent:

Contact Person: Cassie Lee
Company: Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
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E-mail: 382198657@qq.com

Date of the summary prepared: August 26, 2026

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: MSL2, MSR2
Review Panel: Neurology
Product Code: GXY, IQZ
Regulation Number: 21 CFR 882.1320
Regulatory Class: II

3. Manufacturer's Legally marketed device information

Sponsor: Zhejiang Qiangnao Technology Co.,Ltd.
Trade Name: Dexus Prosthetics System

Model: MSL1, MSR1
Common Name: Powered, External Upper Limb Prosthetic System
Classification Name: Cutaneous electrode
510(K) Number: K220002
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 to the neural myoelectric signal collected from the skin's surface to realize the control of the upper limb prosthetic device. The collected neural myoelectric signal are processed through specific algorithms to achieve 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, IEC 60601-1-6 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

Compared with the predicate devices (Manufacturer's Legally marketed device), the subject device is the same in technical design, intended use/indications for use, functions, etc. And the differences between the subject device and predicate devices do not raise new questions of safety or effectiveness. Please refer to the detailed Substantial Equivalence Comparison of the subject device and predicate devices in the following table.

Comparison in Detail(s):

Elements of Comparison	**Subject Device**	**Predicate Device** (Manufacturer's Legally marketed device)	**Verdict**
Manufacturer	Zhejiang Qiangnao Technology Co.,Ltd	Zhejiang Qiangnao Technology Co.,Ltd	--
Trade Name	Dexus Prosthetic System	Dexus Prosthetic System	--
Models	MSL2, MSR2	MSL1, MSR1	--
510(k) Number	Pending	K220002	--
Classification Name	Cutaneous electrode	Cutaneous electrode	Same

Classification Product Code	GXY	GXY	Same

Elements of Comparison	Subject Device	Predicate Device (Manufacturer's Legally marketed device)	Verdict
Subsequent Product Code	IQZ	IQZ	Same
Intended Use / Indications for Use	The Dexus Prosthetic System is to be used exclusively for external prosthetic fittings of the upper limbs.	The Dexus Prosthetic System is to be used exclusively for external prosthetic fittings of the upper limbs.	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.	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)	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)	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
Power Source	Rechargeable battery	Rechargeable battery	Same

Adjustment software	No	No	Same
Software/Firmware/Microprocessor Control?	Yes	Yes	Same
Terminal device (e.g., Hand, wrist or elbow) included?	Yes	Yes	Same

Elements of Comparison	**Subject Device**	**Predicate Device** (Manufacturer's Legally marketed device)	**Verdict**
Wireless Communication	No	No	Same
Technological Characteristics - Hand			
Operating temperature	+5°C to +40°C	+5°C to +40°C	Same
Weight	530g	530g	Same
Max. Gripping force	12N (all mode)	12N (all mode)	Same
Max. Grip Speed	150mm/s	150mm/s	Same
Max. Opening Width	106mm	106mm	Same
Technological Characteristics - Electrode			
Dimensions	34.5mm x 16mm x 11.5mm	34.5mm x 16mm x 11.5mm	Same
Operating temperature	0°C - 40°C	0°C - 40°C	Same
Material	Polycarbonate: PC2858, Thermoplastic Elastomer: TM5ADT and Metal Pieces: C1SQIN	Polycarbonate: PC2858, Thermoplastic Elastomer: TM5ADT and Metal Pieces: C1SQIN	Same
Contact area	Copper plated	Copper plated	Same
Frequency bandwidth	80 - 500 Hz	80 - 500 Hz	Same
Adjustment	None	None	Same
Installation	Suction socket	Suction socket	Same
Technological Characteristics - Battery			
Chemistry	Li Ion	Li Ion	Same
Number of cells	2	2	Same

Nominal voltage	7.2V	7.4V	Similar Note 1
Battery capacity	3000mAh	2200mAh	Similar Note 1
Charging time	Max.4.0h	Max.3.0h	Similar Note 1
Battery weight	110g	110g	Same
Battery dimensions (L*W*H) (mm)	68x38x20	68x38x20	Same
Installation	Integrated	Integrated	Same
Safety and Performan :e Testing			
Electrical Safety	IEC 60601-1 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-11	Same
Elements of Comparison	**Subject Device**	**Predicate Device** (Manufacturer's Legally marketed device)	**Verdict**
Electromagnetic Compatibility	IEC 60601-1-2	IEC 60601-1-2	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10	Same

Note 1:

Although the "Nominal voltage", "Battery capacity" and "Charging time" of the subject device are different from the predicate device, all of them meet the requirements of safety and performance standards IEC 60601-1, IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2 and IEC 62133-2. 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 (Manufacturer's Legally marketed device, K220002). 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.