April 15, 2024

Infinite Biomedical Technology LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K240884
Trade/Device Name: Glide (91000-GL-X)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 29, 2024
Received: April 1, 2024

Dear Prithul Bom:

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.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director
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)*

K240884

Device Name

Glide

Indications for Use *(Describe)*

Glide is to be used exclusively for exoprosthetic fittings of the upper limb

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
Glide

1. SUBMITTER'S INFORMATION

Name/Manufacturer	Infinite Biomedical Technologies, LLC
Address	8 Market Pl, Suite 500, Baltimore, MD 21202
Phone Number	(443) 451-7175
Fax Number	(443) 451-7179
Contact Person	Rahul Kaliki, PhD, Chief Executive Officer
Date Prepared	February 13, 2024

2. CORRESPONDENT CONTACT

Contact Person	Damini Agarwal
Company	Infinite Biomedical Technologies, LLC
Email	Damini@i-biomed.com

3. DEVICE INFORMATION

Trade Name	***Glide***
Common Name	Powered, External Upper Limb Prosthetic System
Classification	Cutaneous Electrode (21 CFR § 882.1320)
Product Code	GXY (Electrode, Cutaneous)
Subsequent Product Code	IQZ (Hand, External Limb, Component, Powered)

4. PREDICATE DEVICE INFORMATION

Device Name	Axon-Bus Prosthetic System
Common Name	Powered, External Upper Limb Prosthetic System
Device Manufacturer	Otto Bock Healthcare Product GmbH
Classification Name	Cutaneous Electrode (21 CFR § 882.1320)
Classification Product Code	GXY (Electrode, Cutaneous)
510(k) Number	K123795

5. REFERENCE DEVICE INFORMATION

Device Name	Element System with IBT Electrodes
Common Name	Powered, External Upper Limb Prosthetic System
Device Manufacturer	Infinite Biomedical Technologies, LLC
Classification Name	Cutaneous Electrode (21 CFR § 882.1320)
Classification Product Code	GXY (Electrode, Cutaneous)
510(k) Number	K173571

6. INDICATIONS FOR USE STATEMENT

Glide is to be used exclusively for exoprosthetic fittings of the upper limb.

7. DEVICE DESCRIPTION

Glide is a surface electromyography (EMG) electrode and control system intended to be used with an upper limb prosthesis. ***Glide*** detects surface EMG signals using IBT Electrodes V2 placed on the user's skin. These signals are processed by ***Glide*** and are used to drive the upper limb prosthesis.

Glide is compatible with industry standard domes. ***Glide*** does not have any direct or indirect skin contacting parts. ***Glide*** is compatible with most hands, wrists, and elbows that accept industry standard inputs. ***Glide*** accepts power from the prosthesis batteries and outputs control signals to hands, wrists, and other prosthetic components. The components of ***Glide*** are assembled into the prosthesis by a certified prosthetist or trained technician according to the individual needs of the amputee. ***Glide*** is a reusable single patient use device.

Glide does not replace or modify any functionality of connected prosthetic components.

Adjustments to the ***Glide*** components can be performed through Bluetooth data transfer using the IBT Control Application. The IBT Control Application runs on the iPad OS platform and allows the prosthetist to adjust the settings of the system, such as assignment of input filtered signal to prosthesis movements, adjustment of gains, etc.

Glide components:

- Core2 Controller (90010)
- Output Cable (90020-XX)
- IBT Remote Dome Electrodes (upto 8)
- Electrode Cables
- IBT Control Application
- Core2 Fabrication Kit (94001)
- Documentation
- Dome Fabrication Kit (optional)

8. PRINCIPLES OF OPERATION FOR GLIDE

Glide is an alternate to the two-site direct control methods used in commercially available prosthesis control systems. ***Glide*** processes inputs from two to eight electrodes to drive a prosthesis into multiple movements without the use of traditional triggers and/or calibration. ***Glide*** uses similar control options as that of the predicate device and enables the use of those control options for more than 3 electrodes.

9. Comparison of Technological Characteristics

Table 1 provides a summary of technological characteristics of the product in comparison to the predicate device.

Manufacturer	**Infinite Biomedical Technologies, LLC**	**Ottobock Healthcare Product GmbH**	**Predicate Device Comparison**
Trade Name	Glide	Axon Bus Prosthetic system	
System			
Indications for Use	Glide is to be used exclusively for exoprosthetic fittings of the upper limbs.	The Axon Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.	Same[1]
Power Source included?	No	Yes	Differs [2]

Manufacturer	Infinite Biomedical Technologies, LLC	Ottobock Healthcare Product GmbH	Predicate Device Comparison
Trade Name	Glide	Axon Bus Prosthetic system	
Terminal device (Hand, Wrist or Elbow) included?	No	Yes	Differs [3]
Wireless communication	Bluetooth®	Bluetooth®	Same
Clinical Software Tool	Yes IBT Control Application	Yes Axon Soft	Similar[6]
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Similar[6]
Power Input Voltage	7.4 – 16 VDC	11.1 VDC	Differs [4]
Output Signal	Analog and Digital	Digital	Similar[3]
Control Unit			
Processing Unit **(L x W x H)**	Core2 Controller 59 x 27.8 x 9.8mm	Axon Master 53 x 25 x 9 mm	Similar[7]
Weight	10g	15g	Similar[7]
Control options	Multiple	Multiple	Similar[6]
Electrode			
Electrode **(L x W x H)**	IBT Electrode V2 26.8 x 14.8 x 7.5mm	Electrode 27 x 18 x 9.5 mm	Similar[5]
Temperature range (use)	-10° to 60°C	-15° to 60°C	Similar[5]
Type	Remote	Cased	Differs[5]
Housing Material	Nylon12 (PA12)	Plastics (ASA)	Differs[5]
Contact Area	No skin contacting part Compatible with industry standard domes	Titanium (Grade 1)	Differs[5]
Number	Up to 8	Up to 2	Differs[5]
Bonding Agent	Cyanoacrylate	Cyanoacrylate	Same
Signal processing	Digital	Analog	Differs[5]
Frequency Bandwidth	90 - 300 Hz	90 – 450 Hz	Similar[5]
Adjustment	Digital Gain 1-10	Analog Gain 1 - 7	Differs[5]
Installation	Suspension arms / suction socket	Suspension arms / suction socket	Same

Table 1: Technological Summary

10. Substantial Equivalence Discussion

IBT believes that ***Glide*** is substantially equivalent to specific parts of Ottobock's Axon-Bus Prosthetic System (K123795). A comparison of the indications for use, technology, and performance is provided herein to support this determination. For instances where technological differences are identified in the previous section, additional discussion below describes how these differences do not raise new or different questions of safety and effectiveness. When appropriate, performance data is cited to provide evidence that the subject device is as safe and as effective as the legally marketed predicate device. Glide also uses the Element System with IBT Electrodes (K173571) as the reference device. This is because IBT Electrodes V2 uses similar digital gains and digital signal processing as the reference device.

1. Indications for Use

Both the subject device, the predicate device are intended to be used exclusively for exoprosthetic fittings of upper limbs. Both products are prescription-use devices, intended to be installed by a certified prosthetist or trained technician.

Table 2. Indications for Use

Characteristic	Subject Device Glide System	Predicate Device (K123795) Axon Bus Prosthetic System
Indications for Use	Glide is to be used exclusively for exoprosthetic fittings of the upper limbs.	The Axon Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.

Technology

Glide contains similar components to the Axon Bus Prosthetic System (K123795), as delineated in Table 3.

Table 3: System Components

Component	Subject Device Glide	Predicate Device (K123795) Axon-Bus Prosthetic System
Terminal device	Compatible with multiple prosthetic components including Michelangelo Hand	Michelangelo Hand
Passive wrist flexion device	Compatible with multiple prosthetic components that include passive wrist flexion within the device.	AxonFlexion Adapter
Passive wrist rotation device	Compatible with multiple prosthetic components including AxonRotation	AxonRotation Adapter
Passive elbow joint	Compatible with multiple prosthetic components including AxonArm	AxonArm
Battery	Compatible with multiple prosthetic powering systems including AxonEnergy Integral	AxonEnergy Integral
Charger	N/A	AxonCharge
Processing unit	Core2 Controller	Axon Master
EMG electrode	IBT Electrode V2	Cased Electrode (PN:13E200=60)
Adjustment software	IBT Control Application	AxonSoft

Component	Subject Device Glide	Predicate Device (K123795) Axon-Bus Prosthetic System
Prosthetic glove	N/A	AxonSkin

Based upon a technical review of both systems, IBT has identified the following technical differences:

- Power Source
- Terminal Devices
- Power Input voltage
- Electrode Features

These areas are described and discussed herein.

2. Power Source

Description & Comparison: Glide does not include a power source. The predicate device includes a power source called AxonEnergy Integral.

Discussion: Glide draws power from the prosthesis batteries and hence does not include a specific power source. Similar to other prosthetic components, Glide is designed to work with all industry standard battery systems. As a result, this difference in inclusion of a power source has no impact on the safety or effectiveness profile of the system.

3. Terminal Device

Description & Comparison: Glide is compatible with multiple prosthetic components including those of the predicate device. The predicate device is compatible with only specific prosthetic components.

Discussion: Glide is designed to be compatible with all industry standard prosthetic components. They can be broadly classified into 3 main categories – analog, motor and digital – hands, wrists and elbows. IBT has run verification and validations on each category of devices to confirm the safety and effectiveness of the same.

Further, the subject device outputs analog, digital, and motor signals to control prosthetic components. In comparison, the predicate device outputs only digital signals. However, the subject device has been designed and adequately verified and validated to be compatible with all industry standard analog, motor and digital prosthetic components of hands, wrists, and elbows. Therefore, the difference in output signals is not a concern.

4. Power Input Voltage

Description & Comparison:	The Glide has an input voltage range of 7.4 – 16V DC. The predicate device has an input voltage of 11.1VDC.
Discussion:	The input voltage range of Glide matches that of industry standard prosthesis powering systems. Since Glide draws power from the prosthesis, Glide has been tested to an input voltage range that matches that of industry standard prosthesis powering systems. The predicate device draws power from only a single power source and as a result, it is rated such. Additionally, Glide is also compatible with the power source of the predicate device. This difference in input voltage has no impact on the safety or effectiveness profile; especially since it was tested as part of the 60601 testing for Glide.

5. Electrode Features

Description & Comparison:	Glide includes up to 8, remote-style electrodes with digital gains and signal processing. The Glide system does not have any skin contacting part and is compatible with industry standard skin contacting domes. Alternatively, the Axon-Bus Prosthetic system uses up to 3, cased-style electrodes with analog gains and a skin contacting part made up of titanium. Additionally, Glide includes electrodes that have a L x W x H of 26.8 x 14.8 x 7.5mm whereas the predicate device uses electrode with dimensions of 27 x 18 x 9.5 mm. Also, electrodes in Glide are tested from -10° to 60°C whereas the predicate device electrodes are tested from -15° to 60°C. Moreover, Glide has a frequency bandwidth of 90 – 300 Hz, whereas the predicate device has a frequency bandwidth of 90 – 450 Hz.
Discussion:	Glide is designed to use up to 8 electrodes, and the safety and effectiveness of 8 electrodes is like that of 1 electrode. Moreover, due to compatibility with industry standard domes, Glide itself does not have any skin contacting parts, and thus the safety and effectiveness is comparable to that of cased electrodes of the predicate device. Additionally, Glide uses digital gains and signal processing similar to that of the reference device (K173571) which offers no difference in the safety and effectiveness profile of the electrode. Moreover, Glide uses electrodes that have similar dimensions than that of the predicate system, in fact they are smaller to not add additional weight or bulk to the prosthesis. The same has been verified and validated and hence is not a concern. Electrodes in Glide have been tested to the latest 60601 standards for safety testing, which also includes testing at the specified temperature

range. Since Glide passed all 60601 testing successfully, the minor difference in temperature does not present a safety or efficacy concern.

Glide and the predicate device use similar bandwidths for the electrodes. The 90 – 350 Hz range captures the bulk of EMG signals, and since neither Glide nor the predicate device use frequency dependent signal features, the minor difference in bandwidth does not result in any safety and efficacy concerns. This is further evidenced by the extensive verification and validation testing performed on Glide.

In addition to the technical differences, IBT has also identified a key technical similarity in the control options offered by both systems. It is described and discussed herein.

6. <u>Control Options:</u>

Description & Comparison:	Glide provides various control options to the user, similar to that of the predicate device. The control options include use of sustained electrode signal with proportional range, ability to adjust the working range of the signal, use of fast vs slow contraction signals, co-contraction based control and four channel control. The predicate device allows for use of the above control schemes with only up to 3 electrodes; however, Glide applies the above control schemes for up to 8 electrodes using vector summation control. Adjustment to the settings of the control scheme is performed through the IBT Control Application in Glide which is like the AxonSoft software in the predicate device. Both systems run the control scheme through firmware programmed on a microprocessor.
Discussion	Glide expands the control options provided by the predicate device for use with up to 8 electrodes through a vector summation method. The native functionality is similar and is only presented to the user visually in a different manner that also allows for the function to be applied to up to 8 electrodes. Since the native functionality is similar in both systems, and has been verified and validated thoroughly, there is no additional safety or effectiveness concern. Both the subject device and the predicate device allow clinicians to view EMG signals and adjust signal thresholds. However, each software app is proprietary to its own device system. The subject device IBT Control application locally stores device configuration and control option settings. It does not store any Personal Identifiable Information (PII) Data, nor does it connect to the internet. It has undergone extensive software verification and validation. Therefore, this difference in the app is minor and not a concern. Both systems run the control scheme through firmware programmed on a microprocessor. The microprocessor used and the firmware it runs is proprietary to its own device system. However, the same control scheme is implemented in the firmware of both the subject and predicate device. The subject has undergone extensive software verification and

validation. Therefore, this difference in the firmware/microprocessor is minor and is not a concern.

7. <u>Control Unit:</u>

Description & Comparison:	Glide has a processing unit with L x W x H of 59 x 27.8 x 9.8mm whereas the predicate device processing unit has L x W x H of 53 x 25 x 9 mm. Additionally, the Glide control unit has a weight of 10g and the predicate device control unit has a weight of 15g.
Discussion	The dimensions of both the subject and the predicate device processing units are similar, in fact, the volume of Glide is lesser than the volume of the predicate device to not add additional weight or bulk to the prosthesis. The same has been verified and validated and hence is not a concern. Similarly, the weight of both the subject and the predicate device are similar, in fact, the weight of Glide is lesser than the weight of the predicate device to not add additional weight or bulk to the prosthesis. The same has been verified and validated and hence is not a concern.

11. Performance Data

IBT has conducted performance tests to demonstrate the safety and effectiveness of Glide, as compared to the predicate device (see Table below)

Performance Test	**Subject Device** **Glide**	**Comparison to Predicate Device** **Axon-Bus Prosthetic System (K123795)**
Software V&V and Design V&V	Passed Internal Testing Regimen	As with any device, the predicate would also have been tested to determine if user and device requirements are met. There is no publicly available information on the same.

Glide was tested to ensure its safety and effectiveness. The following Performance Standards were used for performance testing of Glide:

Category	**No**	**Title**	**Version**	**Comparison to Predicate Device (K123795)** **Axon-Bus Prosthetic System**
Safety	IEC/EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005, IEC 60601 1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	Predicate was tested to 2005 standards
	IEC 60601-1-11	General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	Predicate was not tested to this standard
Electro-magnetic Compatibility	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2:2015+A1:2021,	Predicate was tested to 2007 standards

Glide also underwent design verification and validation, software verification and validation, and usability testing to demonstrate its ability to achieve its intended use safely and effectively. The tables below outline the validation testing that was performed on Glide.

Validation testing on Glide

Test Name	Result
Installation of Core2	Pass
IBT Use of UI	Pass
Practitioner Use of UI	Pass
Patient Use of UI	Pass
Patient use of prosthetic component	Pass
Battery Life	Pass
Use with region specific noise	Pass
Installation and use of IBT electrodes	Pass
Lifetime and Reliability Testing	Pass
Packaging Drop Test	Pass

12. Conclusions

Based upon the discussion provided herein and the supporting data, IBT believes that ***Glide***, is as safe and effective as the predicate device (Axon Bus Prosthetic System, K123795) for its intended use, making it substantially equivalent to a legally marketed predicate device.