March 21, 2018

Infinite Biomedical Technologies, LLC
Rahul Kaliki
CEO
1101 E 33rd Street, Suite E305
Baltimore, Maryland 21218

Re: K173571
Trade/Device Name: Element System with IBT Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: January 19, 2018
Received: January 23, 2018

Dear Rahul Kaliki:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K173571

Device Name
Element System with IBT Electrodes

Indications for Use *(Describe)*
The Element system is intended to be used exclusively for myoelectric 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
Element System with IBT Electrodes

1. SUBMITTER'S INFORMATION

Name/Manufacturer	Infinite Biomedical Technologies, LLC
Address	1101 E. 33rd Street, Suite E305, Baltimore, MD 21218
Phone Number	(443) 451-7177
Fax Number	(443) 451-7179
Contact Person	Rahul Kaliki, PhD, Chief Executive Officer
Date Prepared	March 21, 2018

2. DEVICE INFORMATION

Trade Name	Element System with IBT Electrodes
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)

3. PREDICATE DEVICE INFORMATION

Device Name	Axon-Bus Prosthetic System
510(k) Number	K123795

4. INDICATIONS FOR USE STATEMENT

The Element system is intended to be used exclusively for myoelectric exoprosthetic fittings of the upper limb.

5. DEVICE DESCRIPTION

The Element system is a surface electromyography (EMG) electrode system that is to be used with upper limb prosthetic devices. Element outputs standard envelop EMG signals detected from EMG electrodes (IBT Electrodes) placed on the user's skin. These signals are used as inputs by connected prosthetic devices, such as hands, wrists or elbows. The Element system is an alternative to standard suction socket myoelectrodes, with the advantages of a lower profile, digital signal processing, and wireless gain adjustment. Element does not replace or modify any functionality of connected prosthetic components.

Element is compatible with most hands, wrists, and elbows that accept standard analog EMG electrode inputs. The Element system is typically sold with three-port kidney-style output connectors, however alternative connectors may be used to ensure compatibility with other terminal devices. The Element system accepts power from IBT's FlexCell Battery system and outputs control EMG signals to hands, wrists, or other prosthetic components. The Element system is installed in the prosthesis by a trained prosthetist and connected to prosthetic components selected to meet the needs of the individual user.

System components:

- IBT Electrodes (up to 2)
- Signal Processing Box
- Element Desktop Software

6. TECHNOLOGICAL CHARACTERISTICS

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

Table 1: Technological Summary

Manufacturer	**Infinite Biomedical Technologies, LLC**	**Otto Bock Health Care Product GmbH**	**Device Comparison**
Trade Name	Element System with IBT Electrodes	Axon bus Prosthetic System	
System			
Power Source included?	No	Yes	Differs
Terminal device (Hand, Wrist or Elbow) included?	No	Yes	Differs
Wireless communication	Bluetooth®	Bluetooth®	Same
Clinical Software Tool	Yes Element Application	Yes AxonSoft	Similar
Software/Firmware/ Microprocessor Control?	Yes	Yes	Similar
Input Voltage	5 to 10 VDC	11.1 VDC	Differs
Output Signal	0-5 V analog	0-5 V analog	Same
Processing Unit			
Processing Unit (L x W x H)	Signal Processing Box 38 x 23 x 8 mm	AxonMaster 53 x 28 x 9 mm	Similar
Control options	None	Multiple	Differs
Signal Smoothing	Yes	No	Differs
Electrode			
Electrode (L x W x H)	IBT Electrode 29 x 17 x 7	Electrode 27 x 18 x 9.5 mm	Similar
Temperature range (use)	-10°C to 50°C	-15°C to 60°C	Similar
Housing Material	Plastics (ABS/PC Blend)	Plastics (ASA)	Similar
Contact Area	Titanium (Grade 1)	Titanium (Grade 1)	Same
Bonding Agent	Cyanoacrylate	Cyanoacrylate	Same
Signal processing	Digital	Analog	Differs
Frequency Bandwidth	90 - 500 Hz	90 - 450 Hz	Similar
Adjustment	Digital gain 1-7	Potentiometer 1-7	Differs
Installation	suspension arms / suction socket	suspension arms / suction socket	Same

7. Substantial Equivalence Discussion

IBT believes that its **Element** system with **IBT Electrodes** is substantially equivalent to specific parts of the Ottobock Axon-Bus Prosthetic System (K123795). A comparison of intended use, indications for use, technology, and performance is provided herein to support this determination. For instances where technological differences are identified, additional discussion 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.

Intended Use and Indications for Use

Both the subject device and the predicate device aim to detect, process, and transmit physiological signals (detected via surface electrodes), providing them to a downstream prosthetic device. Both products are prescription use devices, intended to be installed by a prosthetist or trained clinician.

From a clinical perspective, the **Element** system with **IBT Electrodes** is intended to be used with upper limb exoprosthetic fittings, exclusively. This clinical usage profile is identical to the predicate device.

Table 2. Intended Use and Indications for Use

Characteristic	Subject Device Element System with IBT Electrodes	Predicate Device (K123795) Axon-Bus Prosthesis System
Intended Use	Detect, process, and transmit physiological signals for use with a prosthesis	Same as subject device
Indications for Use	The Element system is intended to be used exclusively for myoelectric exoprosthetic fittings of the upper limb.	The Axon-Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.

Minor differences in the written text do not affect the meaning (in other words, they are semantics).

Technology

The **Element** system contains a subset of components within the Axon-Bus Prosthetic System (K123795), as delineated in Table 3.

Table 3: System Components

Component	Subject Device Element System	Predicate Device (K123795) Axon-Bus Prosthesis System
Terminal device	N/A	Michelangelo Hand
Passive wrist flexion device	N/A	AxonFlexion Adapter
Passive wrist rotation device	N/A	AxonRotation Adapter
Passive elbow joint	N/A	AxonArm
Battery	N/A	AxonEnergy Integral
Charger	N/A	AxonCharge
Processing unit	Signal Processing Box	AxonMaster
EMG electrode	IBT Electrode	Electrode
Adjustment software	Software Application	AxonSoft
Prosthetic glove	N/A	AxonSkin

IBT is only claiming equivalence to the predicate's components that are comparable to or part of the **Element** system. Based upon a technical review of both systems, IBT has identified the following technical differences:

- Digital Signal Processing
- Digital Gain Adjustment Software
- Signal Smoothing
- Control Options
- Terminal Options
- Battery Characteristics
- Electrode Materials
- Electrode Size
- Software

These areas are described and discussed herein.

Digital Signal Processing

Description & Comparison:	The **IBT Electrodes** digitize the signals at the electrode site using an analog front end (AFE) chip. The AFE samples the raw EMG signals with a high-resolution ADC. By digitizing the signal near the site of the electrode contacts, this system architecture reduces the potential for external noise sources to corrupt the EMG signals. The predicate Axon-Bus Prosthetic System Electrodes only use analog components in its design.
Discussion:	Digital signal processing was incorporated to reduce noise corruption and allow for further signal processing downstream. These low-power components also are protected throughout the circuit layout with appropriate ESD protective components. The deviation does not result in any additional risk to the user. Both subject and predicate devices need to meet electrical safety and electromagnetic compatibility requirements.

Digital Gain Adjustment Software

Description & Comparison:	The **Element** system allows for wireless adjustments of gain and further signal processing at the downstream Signal Processing Box. Specifically, the Signal Processing Box includes a microcontroller that communicates with the electrodes, processes the EMG signals, and outputs envelope EMG signals to connected prosthetic components. The Signal Processing Box contains a Bluetooth module, which allows the controller to communicate with a software application developed in Java called the **Element Application**. The user (clinician) can visualize EMG signals and adjust electrode gains through this mechanism. The predicate Axon-Bus Prosthetic System Electrode has a gain that can be adjusted through a potentiometer on the back of the electrode.
Discussion:	Access to the gain adjustment can be difficult to reach for prosthetists and, often times, they must create holes in the exterior shell and socket of the prosthesis to enable access to the gain adjustment, creating high stress areas in the material as well as making the prosthesis vulnerable to debris and liquids. The **Element** system does not have a physical manipulator to adjust the gains. Instead, the adjustments can all be made through the **Element Application** software. Verification and Validation tests were conducted to ensure that the Element System's gain

adjustment method resulted in an equivalent signal output to the predicate device.

Although the methodology is different, both systems contain a mechanism to adjust the signal gain.

Signal Smoothing

Description & Comparison: The **Element** system includes functionality to change the smoothness of the EMG signal. This feature is adjusted through the **Element Application**. The smoothing function increases the stability of the EMG signal at the cost of responsiveness. The higher smoothness allows for users to control their signal amplitude more steadily if they have trouble maintaining extended signals. A lower smoothness allows the user to achieve triggers for degree-of-freedom switching more easily. The smoothness function does have limits to ensure that the reduced responsiveness does not significantly impede the performance of the electrodes when used with a prosthetic device (see draft instructions for use). Default settings can be used to mimic similar signal qualities of the predicate device.

The predicate device does not include a smoothing feature in the design, however other electrodes on the market include this functionality.[1]

Discussion: The smoothness function is a feature to aid prosthetists in making adjustments unique to the individual, similar to how the predicate device provides various control options depending on the type of signals generated by the patient/end user. The risks involved in this customization step are no different between subject and predicate devices.

Control Options

Description & Comparison: Complete prosthetic systems typically contain a set of "control options" that allow modification of the way a user would operate the prosthetic device. This may include "first-over" versus "differential" activation of a degree of freedom or an option to reverse input directions. It may also specify if inputs besides EMG are used in the prosthesis. The Axon-Bus Prosthetic System (predicate under K123795) contains this functionality, whereas the subject **Element** system does not.

Discussion: **Element** does not provide control mechanisms for the downstream prosthetic system; the output of the **Element** system is similar to that of the predicate device EMG Electrode, which provides filtered signals to the prosthesis based on user inputs. Therefore, the device has inherently simpler operation than the predicate. This deviation does not raise any additional concerns with respect to risk to the user.

Terminal Options

Description & Comparison: The **Element** system does not include a terminal device, passive wrist flexion/extension devices, or an elbow joint. These options are available on the predicate device. Instead, the **Element** system outputs its signal

[1] For example, the Triad Electrodes from Motion Control, Inc. have a smoothness function. This particular functionality from Motion Control is part of a Class I, 510(k) exempt component.

through industry-standard 3-pin kidney shaped connectors, with an output range exactly the same as other similar electrode devices on the market (including the predicate system's electrode).

Discussion: Both subject and predicate devices need to ensure that the output signal is transferrable to a downstream component. The subject device does this through industry-standard connections. If this specification is met, then the subject device does not introduce new or different questions of safety or effectiveness.

Battery Characteristics

Description & Comparison: The **Element** system does not include a battery and has an input voltage range of 5-10 V. The predicate device uses a rechargeable 11.1 V Li-Ion Battery Pack. This difference is thought to be due to voltage requirements in the Axon-Bus Prosthetic System's Michelangelo Hand, which requires higher voltage than other terminal devices on the market.

Discussion: The input voltage range of the Element system is similar to most electrodes currently sold on the market today. The Element system is only intended to be compatible with a separately sold battery, FlexCell, which is rated at a nominal voltage of 7.4V. This battery system is compatible with most upper limb prosthetic terminal devices on the market. This difference in voltage requirements has no impact on the safety or effectiveness profile.

Electrode Materials

Description & Comparison: The housing of the **IBT Electrode** is manufactured with a PC-ABS blend, whereas the predicate device housing uses ASA. Both products utilize titanium grade 1 electrode contact material. The type of contact, duration of contact, and cleaning profiles are identical.

Discussion: Both subject and predicate devices have patient contacting materials that experience the same use scenarios. The risk of a tissue response to the material used is equivalent, and both products are tested to the applicable parts of ISO 10993.

Electrode Size

Description & Comparison: A specific requirement for certain prosthetic applications is to include electrodes capable of maintaining suction on the patient's limb when the prosthesis is donned. The Element system with IBT Electrodes can maintain a sealed socket with a small form factor.

Discussion: The smaller electrode size could impact installation (maintaining suction) and performance (signal detection). Neither aspect is unique or representative of a new/different question of safety or effectiveness. Testing demonstrated equivalent performance.

Software

Description & Comparison: The **Element** system includes embedded system software within the microprocessor of the Signal Processing Unit and a separate software application**.** The predicate device also has a software application (AxonSoft) and embedded software within the Axon Master and

	Michaelangelo hand. The **Element's** software application is used for viewing signals, gain adjustment, and adjusting smoothness of the EMG signal, whereas the predicate device's software application is used to change control options, adjust the parameters of the control options, and view signals. The **Element's** embedded software is used to process the digital signals (filtering, gain adjustment, smoothness), whereas the embedded software in the predicate device is responsible for both low-level and high-level control functions for the prosthetic hand.
Discussion:	The differing features of the **Element** system's software application and embedded software do not introduce new/different safety or efficacy concerns.

8. Performance Data

The Element system with IBT Electrodes was tested to ensure its safety and effectiveness. The following Performance Standards were used for performance testing of the Element system:

Category	No	Title	Version	Comparison to Predicate Device Axon-Bus (K123795)
Safety	IEC/EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	2012 (IEC)/2006 (EN)	Equivalent
	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	2010	Predicate was not tested to this standard

Category	No	Title	Version	Comparison to Predicate Device Axon-Bus (K123795)
Electromagnetic 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	2007	Equivalent
Biocompatibility	ISO 10993-1	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2009	Equivalent
	ISO 10993-5	Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity	2009	Equivalent
	ISO 10993-10	Biological evaluation of medical devices Part 10: Test for irritation and skin sensitization	2009	Equivalent

The Element system with IBT Electrodes 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 following validation testing was performed on the device:

Test Name	Result
Compatibility with IBT Electrodes	Pass
Simulated installation of Element	Pass
Simulated Use of Element Software and Electrode Placement	Pass
Simulated Use with Commonly used Prosthetic Components	Pass
Lifetime and Reliability Testing	Pass
Testing Report Summary	Pass
Signal Performance during Simulated Use	Pass
Simulated battery life with Element	Pass
Simulated use with Region Specific Noise	Pass
Packaging Drop Test	Pass
Simulated Installation of IBT Electrodes	Pass
Simulated Seal	Pass
Simulated Cleaning	Pass

The Flexcell battery was also tested to ensure its safety and effectiveness. The following Performance Standards were used for performance testing of the FlexCell battery:

Category	No	Title	Version
Safety	IEC 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	2012 (IEC)
	IEC 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	2002 (1st edition)
Transportation	UN38.3	Transportation Testing for Lithium Batteries	ST/SG/AC.10/11/Rev.5/Amend.1 & ST/SG/AC.10/11/Rev.5/Amend.2

The FlexCell battery also underwent design verification and validation and usability testing to demonstrate its ability to function safely and effectively. The following testing was performed on the device:

Test Name	Result
FlexCell Major Component Test	Pass
FlexCell V&V Test Specification Plans	Pass
FlexCell Charger Update V&V Test Plan	Pass
FlexCell Charger IC Update V&V Test Plan	Pass

9. Conclusions

Based upon the discussion provided herein and the supporting data, IBT believes its **Element** system with **IBT Electrodes** are as safe and as effective as the predicate device (Axon-Bus K123795) for its intended use, making it substantially equivalent to a legally marketed predicate device.