Infinite Biomedical Technologies, LLC
Rahul Kaliki
CEO
8 Market Place, Suite 500
Baltimore, Maryland 21202

Re: K182112
Trade/Device Name: Sense System with IBT Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: August 2, 2018
Received: August 6, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182112

Device Name
Sense System with IBT Electrodes

Indications for Use *(Describe)*
Sense System with IBT Electrodes is to be used exclusively for external prosthetic fittings of 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Sense System

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	August 1, 2018

2. DEVICE INFORMATION

Trade Name	Sense 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	COMPLETE CONTROL System
510(k) Number	K162891

4. REFERENCE DEVICE INFORMATION

Device Name	Element System with IBT Electrodes
510(k) Number	K173571

5. INDICATIONS FOR USE STATEMENT

Sense System with IBT Electrodes is to be used exclusively for external prosthetic fittings of upper limbs.

6. DEVICE DESCRIPTION

The Sense System is a surface electromyography (EMG) electrode system designed to enhance control of upper limb prosthetic devices. The Sense System detects EMG signals using the IBT Electrodes (previously approved by the FDA under 510k, K173571). The electrode signals are then processed using a pattern recognition algorithm and translated to output signals that are standardized to be compatible with an array of connected prosthetic devices, such as hands, wrists or elbows. The Sense System does not replace or modify any functionality of connected prosthetic components.

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

Sense System components:

- IBT Electrodes (up to 8)
- Signal Processing Box
- User Interface Software
- Fabrication dummies for electrodes and processing box

7. TECHNOLOGICAL CHARACTERISTICS

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

Table 1: Technological Summary

Manufacturer	**Infinite Biomedical Technologies, LLC**	**Coapt, LLC**	**Device Comparison**	**Reference Device – Infinite Biomedical Technologies LLC**	**Reference Device Comparison**
Trade Name	Sense System with IBT Electrodes	COMPLETE CONTROL System		Element System with IBT Electrodes	
System					
Power Source included?	No	No	Same	No	Same
Terminal device (Hand, Wrist or Elbow) included?	No	No	Same	No	Same
Wireless communication	Bluetooth®	RF Transmitter, Complete Communicator 21.8 x 69.2 x 16.1mm	Differs	Bluetooth®	Same
Clinical Software Tool	Yes User Interface Application	Yes Complete Controlroom	Similar	Yes User Interface Application	Similar
Software/Firmware/ Microprocessor Control?	Yes	Yes	Similar	Yes	Similar
Input Voltage	5 to 10 VDC	5.3-16.8 VDC	Differs	5 to 10 VDC	Same
Output Signal	0-5V analog, 0-3.3V digital and 0-8.2V motor	Analog, motor (ranges unknown)	Unknown	0-5V analog	Similar
Processing Unit					
Processing Unit (L x W x H)	Processing Box 59 x 27.8 x 9.8mm	Complete Controller 66.1 x 25.9 x 13.5 mm	Similar	Processing Box 38 x 23 x 8 mm	Similar
Control options	Pattern Recognition	Pattern Recognition	Same	None	Differs
Input button	None	Complete Calibrate 27.6 x 17.8 x 11.7 mm	Differs	None	Same
Electrode					
Electrode / Amplifier (L x W x H)	IBT Electrode 29 x 17 x 7	Complete Co-Amp 47.8 x 21.4 x 9.6 mm + Cables and metal domes	Similar	IBT Electrode 29 x 17 x 7	Same
Temperature range (use)	-10°C to 50°C	0°C to 35°C	Differs	-10°C to 50°C	Same

Manufacturer	Infinite Biomedical Technologies, LLC	Coapt, LLC	Device Comparison	Reference Device – Infinite Biomedical Technologies LLC	Reference Device Comparison
Trade Name	Sense System with IBT Electrodes	COMPLETE CONTROL System		Element System with IBT Electrodes	
Housing Material	Plastics (ABS/PC Blend)	Unknown	Unknown	Plastics (ABS/PC Blend)	Same
Contact Area	Titanium (Grade 1)	Stainless Steel or gold plated	Differs	Titanium (Grade 1)	Same
Bonding Agent	Cyanoacrylate	Unknown	Unknown	Cyanoacrylate	Same
Signal processing	Digital	Digital	Same	Digital	Same
Frequency Bandwidth	90 - 500 Hz	Unknown	Unknown	90 - 500 Hz	Same
Adjustment	Digital gain 1-7	Digital gain	Similar	Digital gain 1-7	Same
Installation	suspension arms / suction socket	suspension arms / suction socket	Same	suspension arms / suction socket	Same

8. Substantial Equivalence Discussion

The Sense system with IBT Electrodes is substantially equivalent to the Coapt COMPLETE CONTROL System (K162891). 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 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.

The Sense System with IBT Electrodes also uses the Element System with IBT Electrodes (K173571) as the reference device. This is because the Bluetooth module and communication protocol, the UI framework, the electrodes used as well as the recommended power supply are identical to those in the Element System with the IBT Electrode which was previously cleared under K173571.

Indications for Use

Both the subject device and the predicate device are intended to be used exclusively for external prosthetic fittings of upper limbs. Both products are prescription use devices, intended to be installed by a prosthetist or trained clinician.

Table 2. Indications for Use

Characteristic	Subject Device Sense System	Predicate Device (K162891) COMPLETE CONTROL System
Indications for Use	The Sense System is to be used exclusively for external prosthetic fittings of upper limbs.	The COMPLETE CONTROL System is to be used exclusively for external prosthetic fittings of the upper limbs.

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

Technology

The Sense System contains similar components as the COMPLETE CONTROL System (K162891), as delineated in Table 3.

Table 3: System Components

Component	Subject Device Sense System	Predicate Device (K162891) COMPLETE CONTROL System
Processing unit	Signal Processing Box	Complete Controller
EMG electrode	IBT Electrode	Complete Co-amp, with cabling and domes
Adjustment software	User Interface Application	Complete Controlroom
Input Button	Not needed	Complete Calibrate
Communication	Use internal	Complete Communicator

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

- Wireless Communication
- Input Voltage
- Output Signals
- Calibration Method
- Electrode Material and Suction Seal Compatibility

These areas are described and discussed herein.

Wireless Communication

Description & Comparison: The Sense signal processing box communicates with the user interface via Bluetooth® to update the pattern recognition classifier and other parameters. The predicate uses a non-Bluetooth®-based RF wireless technology to do the same.

Discussion: Wireless communication with the user interface is not related to user safety. The use of Bluetooth® in the Sense system does not introduce any additional safety risks over the predicate device. In fact, the Sense System Bluetooth® communication is identical to the previously approved *Element* system (K123759), has been tested extensively and found to be stable. Additionally, the Bluetooth® module has passed FCC requirements.

Input Voltage

Description & Comparison: The Sense System has an input voltage range of 5-10 V. The predicate device has an input range of 5.3-16.8 V.

Discussion: The input voltage range of the Sense System is similar to most electrodes and controllers currently sold on the market today. The Sense System is only intended to be compatible with a separately sold battery, FlexCell, which is rated at a nominal voltage of 7.4V. Many other battery systems are also rated at this voltage. This difference in voltage requirements has no impact on the safety or effectiveness profile; furthermore, compatible components are listed for customers.

Output Signals

Description & Comparison:	The processing box determines what type of signal the Sense System outputs. Sense has a great variety of outputs, which include 0-5V analog, 0-3.3V digital, and 0-8.2V motor signals, all based on compatibility testing with a range of prosthetic components. The COMPLETE CONTROL system does not specifically list the output types, but based on the list of compatible components provided, the system likely have similar analog and motor inputs.
Discussion:	The two systems share a similar list of compatible components, and therefore must have similar output standards. Majority of components listed are compatible with the industry standard 5V output analog electrode. Those that are motor driven have been tested through verifications. Therefore, the outputs of Sense and COMPLETE CONTROL are likely similar. Additionally, both systems use industry standard connection types.

Calibration Method

Description & Comparison:	The Sense System offers users the option to calibrate their pattern recognition algorithm through a user interface. The option of a PC pre-installed with the software is available to reduce the burden on the patient and their practitioner. The predicate device offers an input button connected to the controller that activates a prosthesis-guided calibration session. The PC-based GUI is provided as a back-up only for use by practitioners.
Discussion:	IBT developed the user interface as the main form of calibration in order to allow users more options for their control, including the ability to calibrate only one movement in the classifier Additionally, the user interface provides the option to practice control pre-prosthetically with a virtual arm, allowing patients to practice control before the final prosthesis is completed. The calibration methodology used in the Sense system does not introduce any additional risks related to patient safety.

Electrode Material

Description & Comparison:	The Sense System includes 8 active, encased electrodes which digitizes the signals on board and communicates with the processing box. The contacts are titanium and the plastic is biocompatible. Alternatively, the COMPLETE CONTROL system uses commercially available electrode dome contacts which are typically stainless steel. These are the only components to interface with the skin; signals are processed remotely in the Complete Co-amp.
Discussion:	The IBT Electrodes were designed to be self-contained through early digitization and be easily replaceable in case of damage. Additionally, all materials were selected with reduction of skin irritation in mind. The titanium contacts do not contain nickel, which is a common skin allergy. The electrodes have been tested for and successfully passed biocompatibility. Differences in material and size do not increase risks to the patient.

Suction Seal Compatibility

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 **Sense** system with **IBT Electrodes** can be fabricated into a suction seal socket. The predicate device uses domed electrodes which need to be individually fabricated into a suction socket.
Discussion:	The 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.

9. Performance Data

IBT has conducted performance tests to demonstrate the safety and effectiveness of the Sense system with IBT Electrodes, compared to the predicate device (see Table below)

Performance Test	**Subject Device** **Sense System with IBT Electrodes**	**Comparison to Predicate Device** **Complete Control System (K162891)**
Software V&V and Design V&V	Passed Internal Testing Regimen	As with any device, predicate would also be tested to determine if user and device requirements are met.

The Sense System was tested to ensure its safety and effectiveness. The following Performance Standards were used for performance testing on Sense and the IBT Electrodes:

Category	**No**	**Title**	**Version**	**Comparison to Predicate Device (K162891)** **COMPLETE CONTROL System**
Safety	IEC/EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	2012 (IEC)/2006 (EN)	Similar – predicate was tested to 2007 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	2010	Predicate was not tested to this standard
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

The IBT Electrodes have been previously cleared by the FDA under K173571.

The Sense System 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 Sense with IBT Electrodes.

Validation testing on Sense with IBT Electrodes

Test Name	Result
Simulated installation of Sense	Pass
IBT Use of UI	Pass
Practitioner Use of UI	Pass
Patient Use of UI	Pass
Simulated Use with Prosthetic Components	Pass
Lifetime and Reliability Testing	Pass
Battery Life	Pass
Packaging Drop Test	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

10. Conclusions

Based upon the discussion provided herein and the supporting data, IBT believes that the Sense System, which includes Sense, the IBT Electrodes, and the UI Application, is as safe and as effective as the predicate device (COMPLETE CONTROL System, K162891) for its intended use, making it substantially equivalent to a legally marketed predicate device.