DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 14, 2017

Coapt, LLC
% Carrie Hetrick
Senior Consultant, Regulatory
Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, Texas 78746

Re: K162891
Trade/Device Name: Complete Control System
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY, IQZ
Dated: April 3, 2017
Received: April 6, 2017

Dear Carrie Hetrick:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

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)*
K162891

Device Name
Complete Control System

Indications for Use *(Describe)*
The Complete Control 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

COMPLETE CONTROL System

K162891

1. Submission Sponsor

Coapt, LLC

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Title: Chief Executive Officer

2. Submission Correspondent

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Office Phone: (512) 327.9997

Contact: Carrie Hetrick

Title: Senior Consultant, RA

3. Date Prepared

3 April 2017

4. Device Identification

Trade/Proprietary Name:	COMPLETE CONTROL System
Common/Usual Name:	Cutaneous Electrode
Classification Name:	Electrode, cutaneous
Regulation Number:	21 CFR §882.1320
Product Code:	GXY, Cutaneous electrode

Subsequent Product Code: IQZ, Hand, External Limb Component, Powered

Device Class: Class II

Classification Panel: Neurology

5. Legally Marketed Predicate Device(s)

K123795, Otto Bock Health Care Product GmbH Axon Bus Prosthetic System

6. Indication for Use Statement

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

7. Device Description

The COMPLETE CONTROL System is an advanced control solution designed to enhance the functionality of a powered myoelectric prosthesis for upper extremity amputees. The COMPLETE CONTROL System employs Pattern Recognition technology to acquire, non-invasively, the rich information in muscle signals to enhance the control of industry standard upper extremity prostheses. Patients can achieve intuitive control of their devices, eliminate control switching, and benefit from quick and powerful recalibration. COMPLETE CONTROL simplifies electrode placement and allows a prosthetist to spend less time adjusting system settings and configurations.

The COMPLETE CONTROL System is designed to work seamlessly with most major manufacturers' devices as an easy plug-and-play add-on. COMPLETE CONTROL does not require an additional battery.

The COMPLETE CONTROL System is an embedded system that is used in conjunction with an upper-limb prosthetic device. This device can include any combination of an elbow, wrist, hand or terminal device. It contains several modules, including one for processing surface EMG (CO-AMP), processing and translating the signals (CONTROLLER), along with a controlling training routine (CALIBRATE). Finally, a wireless adapter (COMMUNICATOR) is included with the system setup and is used to provision the entire system.

The COMPLETE CONTROL System contains the following components.

1. Device Interface Cable (clinician-specified termination type)
2. COMPLETE CONTROLLER main processor
3. COMPLETE CALIBRATE patient interface button
4. COMPLETE CO-AMP consolidated EMG amplifier
5. EMG Interface Cable
6. Fabrication aids for the COMPLETE CONTROLLER, COMPLETE CO-AMP, and COMPLETE CALIBRATE
7. Socket cut-out template for the COMPLETE CALIBRATE button
8. COMPLETE COMMUNICATOR USB dongle
9. COMPLETE CONTROLROOM software installation USB dongle

8. Substantial Equivalence Discussion

The following table compares the COMPLETE CONTROL System to the predicate device with respect to indications for use, principles of operation, technological characteristics, and performance. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Coapt, LLC**	**Otto Bock Health Care Product GmbH**	**Device Comparison**
Trade Name	COMPLETE CONTROL System	Axon Bus Prosthetic System	
510(k) Number	To be determined	K123795	Not applicable
Classification Product Code	GXY	GXY	Same
Regulation Number	21 CFR 890.3450	21 CFR 890.3450	Same
Regulation Name	Cutaneous electrode	Cutaneous electrode	Same
Subsequent Product Code	IQZ (Hand, External Limb Component, Powered)	IQZ (Hand, External Limb Component, Powered)	Same
Indications for Use	The COMPLETE CONTROL System is to be used exclusively for external prosthetic fittings of the upper limbs.	The Axon-Bus Prosthetic System is to be used exclusively for exoprosthetic fittings of the upper limbs.	Same
Use/Field of Application	The COMPLETE CONTROL System is suitable for unilateral or bilateral amputations starting with the transradial/ transhumeral amputation level or, in case of dysmelia, for forearm or upper arm fittings.	The Axon-Bus Prosthetic System is suitable for unilateral or bilateral amputations starting with the transradial/ transhumeral amputation level or, in case of dysmelia, for forearm or upper arm fittings.	Same
Conditions of Use	The COMPLETE CONTROL System was developed for everyday use and must not be used for unusual	The Axon-Bus Prosthetic System was developed for everyday use and must not be used for unusual	Same

Manufacturer	Coapt, LLC	Otto Bock Health Care Product GmbH	Device Comparison
Trade Name	COMPLETE CONTROL System	Axon Bus Prosthetic System	
	activities. These activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill, mountain biking) or extreme sports (free climbing, paragliding, etc.) Furthermore, the COMPLETE CONTROL System should not be used for the operation of motor vehicles or motor-driven equipment.	activities. These activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill, mountain biking) or extreme sports (free climbing, paragliding, etc.) Furthermore, the Axon-Bus Prosthetic System should not be used for the operation of motor vehicles or motor-driven equipment.	
Mechanism of Action	The components of the COMPLETE CONTROL System are assembled by a prosthetist according to the individual needs of the amputee.	The components of the Axon-Bus Prosthetic System are assembled by a prosthetist according to the individual needs of the amputee.	Same
Power Requirements	5.3–16.8 VDC 115 mA at 7.4 V	Li-Ion Battery Various (1150/1500)	Differs
Physical Dimensions			
Central Control Unit	***COMPLETE CONTROL ler*** W: 25.9 mm (1.02 in) L: 66.1 mm (2.60 in) H: 13.5 mm (0.53 in)	***AxonMaster*** 53 x 28 x 9 mm	Similar
	Complete Co-Amp W: 21.4 mm (0.84 in) L: 47.8 mm (1.88 in) H: 9.6 mm (0.38 in)		

Manufacturer	Coapt, LLC	Otto Bock Health Care Product GmbH	Device Comparison
Trade Name	COMPLETE CONTROL System	Axon Bus Prosthetic System	
	Complete Calibrate W: 17.8 mm (0.70 in) L: 27.6 mm (1.09 in) H: 11.7 mm (0.46 in) Depth below socket face: 7.6 mm (0.30 in) Protrusion above socket face: 4.0 mm (0.16 in) Socket mounting hole cut-out size: 14 x 24 mm (0.55 x 0.94 in)	27 x 18 x 9.5 mm	Similar
	Complete Communicator W: 21.8 mm (0.86 in) L: 69.2 mm (2.72 in) including USB end-cap H: 16.1 mm (0.63 in)	Not available	Assumed similar
Clinician Software Tool	Yes COMPLETE CONTROL Room Software	Yes Ottobock Software	Similar
Electrical Safety Testing Passed	IEC 60601-1 IEC 61000-4-3 IEC 61000-4-3 IEC 6100-4-8 IEC 60601-1-2 CISPR 11 FCC Part 15	IEC 60601-1 IEC 60601-1-2	Similar

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the COMPLETE CONTROL System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Coapt, LLC completed a number of non-clinical performance tests. The COMPLETE CONTROL System meets all the

requirements for overall design and electrical safety results, confirming that the design output meets the design inputs and specifications for the device.

The COMPLETE CONTROL System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Electrical safety testing per IEC 60601-1
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2

The COMPLETE CONTROL System was tested internally to ensure that it meets device specifications & requirements and operates as intended. The following validation testing was performed on the finished device:

Test Name	**Result**
Cabling Connection Test	Passed
Power On and Boot Test	Passed
Wireless Connectivity and Profile Test	Passed
Inputs Test	Passed
Outputs Test	Passed
Calibration and Pattern Recognition Test	Passed
Feature Extraction Test	Passed
File Save Test	Passed

10. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The COMPLETE CONTROL System, as designed and manufactured, is determined to be equivalent to the referenced predicate device.