



May 24, 2019

Coapt, LLC  
Blair Lock  
Chief Executive Officer  
222 W. Ontario Street, Suite #300  
Chicago, Illinois 60654

Re: K191083

Trade/Device Name: COMPLETE CONTROL System Gen2  
Regulation Number: 21 CFR 882.1320  
Regulation Name: Cutaneous Electrode  
Regulatory Class: Class II  
Product Code: GXY, IQZ  
Dated: April 11, 2019  
Received: April 24, 2019

Dear Blair Lock:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Carlos Peña, PhD, MS  
Director  
OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K191083

Device Name

COMPLETE CONTROL System Gen2

Indications for Use (Describe)

The COMPLETE CONTROL System Gen2 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.

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## Special 510(k) Summary COMPLETE CONTROL System Gen2

### 1. Submitter Information

Manufacturer: Coapt, LLC  
222 W. Ontario St., Suite 300  
Chicago, IL 60654

Contact Person: Blair Lock, MScE, Peng  
Chief Executive Officer

Contact Information: (844)262-7800 x700  
Blair.lock@coaptengineering.com

Date Prepared: May 23<sup>rd</sup>, 2019

### 2. Device Identification

Trade/Proprietary Name: COMPLETE CONTROL System Gen2

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

### 3. Legally Marketed Predicate Device

510(k) Number	Device Name
K162891	Coapt Complete Control System

### 4. Device Description

The COMPLETE CONTROL System Gen2 is an advanced control solution designed to provide the functionality of a powered myoelectric prosthesis for upper extremity amputees. The COMPLETE CONTROL System Gen2 employs pattern recognition technology to non-invasively acquire user-specific muscle signals for the control of industry-standard upper extremity prostheses. Patients can achieve control of their devices, eliminate control switching, and benefit from quick and powerful recalibration. The COMPLETE CONTROL System Gen2 simplifies

electrode placement and allows a prosthetist to spend less time adjusting system settings and configurations.

The COMPLETE CONTROL System Gen2 is designed to work seamlessly with most major manufacturers’ devices as an easy plug-and-play add-on and does not require an additional battery.

The COMPLETE CONTROL System Gen2 is an embedded system that is used in conjunction with an upper-limb prosthetic device. The system has been validated for a specific set of prosthetic elbow, wrist and hand components which are listed in the user manual.

The COMPLETE CONTROL System Gen2 contains the following components:

- COMPLETE CONTROLLER main processor
- Device Interface Cable (clinician-specified termination type)
- EMG Interface Cable (clinician-specified termination type)
- COMPLETE CALIBRATE Button (part of COMPLETE CONTROLLER)
- Fabrication aid for the COMPLETE CONTROLLER
- Socket cut-out template for the COMPLETE CALIBRATE Button
- COMPELTE CONTROLROOM Application
- COMPLETE COMMUNICATOR Dongle

**5. Indication for Use Statement**

The COMPLETE CONTROL System Gen2 is to be used exclusively for external prosthetic fittings of the upper limbs.

**6. Comparison to Predicate Device**

The following table compares the COMPLETE CONTROL System Gen2 to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials used, 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 efficacy based on the similarities to the predicate device.

<b>Manufacturer:</b>	<b>Coapt, LLC</b>	<b>Coapt, LLC</b>	<b>Device Comparison</b>
<b>Trade Name:</b>	COMPLETE CONTROL System Gen2	COMPLETE CONTROL System	
<b>510(k) Number</b>	K191083	K162891	Not applicable
<b>Classification Product Code</b>	GXY	GXY	Same
<b>Regulation Number</b>	21 CFR 882.1320	21 CFR 882.1320	Same
<b>Regulation Name</b>	Cutaneous electrode	Cutaneous electrode	Same
<b>Subsequent Product Code</b>	IQZ (Hand, External Limb Component, Powered)	IQZ (Hand, External Limb Component, Powered)	Same
<b>Indications for Use</b>	The COMPLETE CONTROL System Gen2 is to be used exclusively	The COMPLETE CONTROL System is to be used exclusively for	Same

<b>Manufacturer:</b>	<b>Coapt, LLC</b>	<b>Coapt, LLC</b>	<b>Device Comparison</b>
<b>Trade Name:</b>	COMPLETE CONTROL System Gen2	COMPLETE CONTROL System	
	for exoprosthetic fittings of the upper limbs.	exoprosthetic fittings of the upper limbs.	
<b>Use/Field of Application</b>	The COMPLETE CONTROL System Gen2 is suitable for unilateral or bilateral amputations.	The COMPLETE CONTROL System is suitable for unilateral or bilateral amputations.	Same
<b>Conditions of Use</b>	The COMPLETE CONTROL System Gen2 was developed for everyday use and must not be used for unusual 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.	The COMPLETE CONTROL System was developed for everyday use and must not be used for unusual 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.	Same
<b>Mechanism of Action</b>	The components of the COMPLETE CONTROL System Gen2 are assembled by a prosthetist according to the individual needs of the amputee.	The components of the COMPLETE CONTROL System are assembled by a prosthetist according to the individual needs of the amputee.	Same
<b>Power Requirements</b>	5.0-20.0 VDC 50 mA at 7.4V	5.3-16.8 VDC 115 mA at 7.4 V	Similar
<b>Physical Dimensions</b>			
<b>Central Control Unit</b>	<b><i>Gen2 Complete Controller (with Device Interface and EMG Interface connected)</i></b> W: 60.3 mm (2.37 in) L: 52.2 mm (2.05 in) H: 8.0 mm (0.31 in)	<b><i>Complete Controller</i></b> W: 25.9 mm (1.02 in) L: 66.1 mm (2.60 in) H: 13.5 mm (0.53 in)	Similar

<b>Manufacturer:</b>	<b>Coapt, LLC</b>	<b>Coapt, LLC</b>	<b>Device Comparison</b>
<b>Trade Name:</b>	COMPLETE CONTROL System Gen2	COMPLETE CONTROL System	
	<i>n/a</i>	<b>Complete Co-Amp</b> W: 21.4 mm (0.84 in) L: 47.8 mm (1.88 in) H: 9.6 mm (0.38 in)	Part of Controller
	<b>Gen2 Complete Calibrate Button</b> W: 16.9 mm (0.67 in) L: 26.9 mm (1.06 in) H: 9.6 mm (0.38 in) Depth below socket face: 3.9 mm (0.15 in) Protrusion above socket face: 3.6 mm (0.14 in) Socket mounting hole cut-out size: 12.7 mm (0.5 in) diameter x 22.7 mm (0.89 in) length	<b>Complete Calibrate</b> 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)	Similar
<b>Communication Component</b>	<b>Complete Communicator Dongle</b> W: 15.8 mm (0.62 in) L: 21.8 mm (0.86 in) H: 6.0 mm (0.24 in)	<b>Complete Communicator</b> 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)	Similar
<b>Miscellaneous</b>			
<b>Clinician Software Tool</b>	Yes Complete ControlRoom Software	Yes Complete ControlRoom Software	Similar
<b>Electrical Safety Testing Passed</b>	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 61000-4-3 IEC 61000-4-3 IEC 6100-4-8 IEC 60601-1-2 CISPR 11 FCC Part 15	Same
<b>Housing Material</b>	Polyurethane	Polyjet	Similar

The design of the COMPLETE CONTROL System Gen2 is similar to the predicate and many other offerings on the market. The COMPLETE CONTROL System Gen2, like the predicate device, can be used for external prosthetic fittings of the upper limbs.

The COMPLETE CONTROL System Gen2 and the listed predicate device, are classified as product code: GXY, cutaneous electrodes under 21 CFR 882.1320, with subsequent product code IQZ for hand, external limb component, powered.

The COMPLETE CONTROL System Gen2 and its predicate are solely for exoprosthetic use. The field of use/application is the same for the subject and predicate device. They are both used for the control of myoelectric exoprostheses and are suitable for unilateral or bilateral amputations. The subject and predicate device also share the same conditions for use and must only be used for normal daily activities, as listed in the labeling.

The COMPLETE CONTROLLER contains hardware that is functionally equivalent to the predicate device. Both devices contain electronics that use various algorithms to drive a prosthetic limb. As with the predicate, the COMPLETE CONTROL System Gen2 is designed to operate with a wide range of prosthetic devices. The COMPLETE CONTROL System Gen2 and the predicate COMPLETE CONTROL System are the same in that they are not provided with a power source. They are both rated to functioning at similar voltages. The predicate COMPLETE CONTROL System can operate using a power source between 5.3-16.8 VDC. The subject, COMPLETE CONTROL System Gen2 can operate using a slightly expanded voltage range, from 5.0-20.0VDC, the slightly expanded operating voltage does not raise any concerns of safety or effectiveness, as the subject device has passed electrical safety testing under IEC 60601, and in-house performance testing. Another slight difference between the subject device and the predicate, COMPLETE CONTROL System is the decreased power consumption. The COMPLETE CONTROL System Gen2 uses less than half of the energy as the predicate COMPLETE CONTROL System. This was an optimization of the COMPLETE CONTROL System Gen2 and does not raise any concerns of safety and efficacy as the subject passed all required testing for electrical safety.

The subject and predicate device are also similar in size because they must be able to fit inside of an exoprosthetic socket. The subject device has a slightly smaller footprint than the predicate COMPLETE CONTROL System. This is an optimization to allow the system to have a better fit into an exoprosthetic socket. The slight difference in size between the subject device and predicate does not add or modify any existing risks or raise any concerns of safety and efficacy.

The COMPLETE CO-AMP of the predicate device is not present in the COMPLETE CONTROL System Gen2. Rather, the functions for signal amplification, filtering, and EMG (electromyography) signal transmission are incorporated within the COMPLETE CONTROLLER of the COMPLETE CONTROL System Gen2. The purpose of this change is to decrease the number of parts and optimize space usage within a myoelectric prosthetic. This difference between the subject device and the predicate does not add or modify any existing risks as the subject device has passed all applicable safety and performance testing.

The enclosure material in the predicate COMPLETE CONTROL System (unmodified device) is comprised of Polyjet, whereas the subject COMPLETE CONTROL System Gen2 is comprised of cast Polyurethane plastic. Polyjet is a reliable material as noted in the predicate device and is very applicable for implants. Nonetheless, Cast Polyurethane was chosen for the COMPLETE CONTROL System Gen2 because of its combination of low production cost and high quality finish. The flexibility of the silicone mold also makes designing for undercuts or draft unnecessary. The change in material does not raise any concerns of safety or efficacy, as the COMPLETE CONTROL System Gen2 has passed the same IEC 60601-1 testing for ingress protection and material strength as the predicate, COMPLETE CONTROL System. Also, the change in enclosure material does not affect the biocompatibility of the device since the enclosure is placed within another manufacturer's prosthesis and does not come into contact with the patient.



The subject device provides similar advanced electronic control and algorithms that control the different limb prosthetics. As with the predicate, COMPLETE CONTROL System, the subject device does not include prosthetic limbs.

The COMPLETE CONTROL System Gen2 electronic components are similar to the predicate device and many other offerings on the market. Both devices manage EMG inputs and control signals to drive a prosthetic limb. The use of the same algorithm in the Gen1 and Gen2 versions of the COMPLETE CONTROL System does not raise any concerns of safety or effectiveness.

One of the core software differences between the predicate COMPLETE CONTROL System and the COMPLETE CONTROL System Gen2 is the addition of a mobile app for the user. The mobile app allows the user to easily recalibrate the prosthesis without the requirement of a computer. The COMPLETE CONTROLROOM software that accompanies the COMPLETE CONTROL System Gen2 is designed to be the same as the COMPLETE CONTROLROOM application provided for the predicate device, it is just optimized to now be provided in a mobile application format, in addition to the pc application format.

The COMPLETE CONTROL System Gen2 is similar regarding physical characteristics and design to the COMPLETE CONTROL System (unmodified device). The COMPLETE CONTROL System Gen2 shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate COMPLETE CONTROL System.

## 7. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the COMPLETE CONTROL System Gen2 and in showing substantial equivalence to the predicate device that is subject to this Special 510(k) submission, Coapt, LLC completed a number of non-clinical performance tests. The COMPLETE CONTROL System Gen2 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 Gen2 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 Compatibility (EMC) testing per IEC 60601-1-2

The COMPLETE CONTROL System Gen2 was also 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	Pass
Power On and Boot Test	Pass
Bluetooth Connectivity and Profile Test	Pass

Inputs Test	Pass
Outputs Test	Pass
Calibration and Pattern Recognition Test	Pass
File Save Test	Pass

## 8. Clinical Performance Data

No human clinical testing was required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, 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.

## 9. 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 different questions regarding its safety and effectiveness as compared to the predicate device(s).

The technological characteristics between the COMPLETE CONTROL System Gen2 and predicate are remarkably similar and therefore substantially equivalent. The slight differences between devices do not raise new questions of safety and effectiveness as compared to the predicate as the COMPLETE CONTROL System Gen2 has received passing results for safety testing for electrical safety, electromagnetic compatibility, ingress protection, and mechanical strength; passing results for performance testing for cabling connection, power on and boot, bluetooth connectivity and profile, inputs, outputs, calibration and pattern recognition, and file save; and validation testing with compatible prosthetic devices.

The COMPLETE CONTROL system Gen2, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.