January 11, 2023

Coapt
Blair Lock
CEO
303 W. Institute Pl.
Suite 200
Chicago, Illinois 60610

Re: K223738
Trade/Device Name: Alpha Control Liner System (ACLS)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 14, 2022
Received: December 14, 2022

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/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 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 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,

Tushar Bansal -S

for Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223738

Device Name
Alpha Control Liner System (ACLS)

Indications for Use *(Describe)*
The Alpha Control Liner System is to be used exclusively for exoprosthetic 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.

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

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# Special 510(k) Summary
# Alpha Control Liner System

## 1. Submitter Information

| | |
|---|---|
| Manufacturer: | Coapt, LLC |
| | 303 W. Institute Pl. Suite 200 |
| | Chicago, IL 60610 |
| Contact Person: | Blair Lock |
| | CEO |
| Contact Information: | 844-262-7800 x700 |
| | blair.lock@coaptengineering.com |
| Contract Manufacturer: | WillowWood Global, LLC |
| | 15441 Scioto Darby Rd |
| | Mt. Sterling, OH 43143 |
| Contact Person: | Matthew Wernke, PhD |
| | Research and Development Manager |
| Contact Information: | (740) 869-3377 |
| | matt.wernke@willowwood.com |
| Date Prepared: | December 12, 2022 |

## 2. Disclaimer

The submitting company requests that they are notified should a Freedom of Information Request is made to obtain a copy of this 510k application so that the company can properly identify any confidential information and redact it prior to public release.

## 3. Device Identification

| | |
|---|---|
| Trade/Proprietary Name: | Alpha Control Liner System (ACLS) |
| Common/Usual Name: | Cutaneous Electrode |
| Classification Name: | Electrode, cutaneous |
| Regulation Number: | 21 CFR §882.1320 |
| Product Code: | GXY, Cutaneous electrode |
| Subsequent Product Code: | Not applicable |
| Device Class: | Class II |
| Classification Panel: | Neurology |

## 4. Legally Marketed Predicate Device

| 510(k) Number | Device Name |
|---|---|
| K191083 | Coapt Complete Control System Gen2 |

## 5. Device Description

The Alpha Control Liner System is an interface solution designed to provide the Complete Control System Gen2with amputee muscle contraction signals needed for the pattern recognition algorithms. The Alpha Control System integrates electronics into a fabric covered elastomeric prosthetic liner to non-invasively detect muscle contractions and convert the signals into a digital format. The Alpha Control System is a substitute for the EMG Interface Cable currently provided with the Complete Control System Gen2. Patients can achieve control of their devices and benefit from quick donning and doffing of the prosthesis. The Alpha Control System simplifies electrode placement and allows a prosthetist to spend less time fabricating the prosthesis as well as adjusting system settings and configurations.

The Alpha Control System is used in conjunction with the Coapt Complete Control System Gen2 and does not require an additional battery.

The Alpha Control System contains the following components.

1. Alpha Control Liner (gel-lined user interface)
2. Alpha Control Module (re-packaged Complete CO-AMP consolidated EMG amplifier, Covered under 510(k) number K162891)
3. Module Cap (secures the Module inside the Liner)
4. Alpha Control Lock (socket suspension and connection to Complete Controller)
5. Electrodes (Covered under 510(k) number K190416)
6. Fabrication aids for the Lock

## 6. Indication for Use Statement

The Alpha Control Liner System is to be used exclusively for exoprosthetic fittings of the upper limbs.

## 7. Comparison to Predicate Device

The following table compares the Alpha Control Liner System 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.

| **Manufacturer:** | **Coapt, LLC** | **WillowWood Global LLC** | **Device Comparison** |
|---|---|---|---|
| **Trade Name:** | COMPLETE CONTROL System Gen2 | Alpha Control Liner System | |
| **510(k) Number** | K191083 | K223738 | Not applicable |
| **Classification Product Code** | GXY | GXY | Same |
| **Regulation Number** | 21 CFR 882.1320 | 21 CFR 882.1320 | 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 Gen2 is to be used exclusively for exoprosthetic fittings of the upper limbs. | The Alpha Control Liner System is to be used exclusively for exoprosthetic fittings of the upper limbs. | Same |
| **Use/Field of Application** | The COMPLETE CONTROL System Gen2 is suitable for unilateral or bilateral amputations. | The Alpha Control Liner System is suitable for unilateral or bilateral amputations. | Same |
| **Conditions of Use** | 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 Gen2 should not be used for the operation of motor vehicles or motor-driven equipment. | The Alpha Control Liner 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 Alpha Control Liner System should not be used for the operation of motor vehicles or motor-driven equipment. | Same |
| **Mechanism of Action** | 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 Alpha Control Liner System are assembled by a prosthetist according to the individual needs of the amputee. | Same |
| **Power Requirements** | 5.0-20.0 VDC<br>50 mA at 7.4V | 5.3–16.8 VDC<br>115 mA at 7.4 V | Similar |

| **Manufacturer:** | **Coapt, LLC** | **WillowWood Global LLC** | **Device Comparison** |
|---|---|---|---|
| **Trade Name:** | COMPLETE CONTROL System Gen2 | Alpha Control Liner System | |
| **User-Interface Materials** | Electrodes: 316L Stainless Steel<br><br>Liner: Not applicable | Electrodes: 316L Stainless Steel<br><br>Liner: Tri-block copolymer gel | Same<br><br>Different; Improvement for electrode contact |
| **Miscellaneous** | | | |
| **Clinician Software Tool** | Yes<br>Complete ControlRoom Software | Yes<br>Complete ControlRoom Software | Similar |
| **Electrical Safety Testing Passed** | IEC 60601-1<br>IEC 61000-4-3<br>IEC 61000-4-3<br>IEC 6100-4-8<br>IEC 60601-1-2<br>CISPR 11<br>FCC Part 15 | IEC 60601-1 | Similar |
| **Biocompatibility Testing Passed** | ISO 10993-1 | ISO 10993-1<br>ISO 10993-5<br>ISO 10993-10 | Similar; additional Bio-compatibility testing performed |

The design of the Alpha Control Liner System is similar to the predicate currently on the market. The Alpha Control Liner System is a substitute for one of the components of the predicate device and therefore is intended to work in conjunction with the predicate device. Together, they can be used for external prosthetic fittings of the upper limbs and are suitable for unilateral and 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 Alpha Control Liner System and the listed predicate device are classified as product code: GXY, cutaneous electrodes under 21 CFR 882.1320.

The Alpha Control Liner System contains hardware that is functionally equivalent to the predicate device. Both devices contain electronics that use various algorithms to process surface electromyography signals into a digital signal that can be used by the pattern recognition algorithm to control a prosthetic limb. The Alpha Control Liner System is designed to operate with the predicate device. The Alpha Control Liner System and the predicate 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 system can operate using a power source between 5.0-20.0VDC. The subject Alpha Control Liner System can operate using a slightly narrower voltage range, from 5.3-16.8 VDC. The slightly narrower operating voltage does not raise any concerns of safety or effectiveness, as the

subject device has passed electrical safety testing under IEC 60601-1, and in-house performance testing.

Another slight difference between the subject device and the predicate, Complete Control System Gen2 is the increased power consumption. The Complete Control System Gen2 uses less than half of the energy as the subject Alpha Control Liner System. This does not raise any concerns of safety and efficacy as the subject passed all required testing for electrical safety under IEC 60601-1, and in-house performance testing.

The subject and predicate device differ slightly in their interface materials. The predicate device used an EMG Interface Cable to connect the electrodes to the controller electronics. This cable is routed on the outside of the socket by the prosthetist treating the patient. The subject Alpha Control Liner System suspends the cable pathways into a tri-block copolymer gel, fabric covered liner which is worn by the patient. This is an improvement to allow more consistent contact of the electrodes and skin within an exoprosthesis socket. This improvement is possible because the elastic properties of the elastomer and fabric allow the liner to stretch over the patient's limb and therefore have a constant pressure keeping the electrodes in contact with the skin. Since the Alpha Control Liner is worn by the patient, it must pass the signal to the socket. To best preserve the sEMG signals, the Alpha Control liner includes electronics that convert the sEMG signals to a digital signal before passing to the socket. The functions for signal amplification, filtering, and EMG (electromyography) signal transmission of the Alpha Control Liner System are based on the same design of the predicate device. This does not add or modify any existing risks as the subject device has passed all applicable safety and performance testing.

The predicate, Complete Control System Gen2 is used with passivated 316L stainless steel electrodes (K190416). This is the for the electrodes (K190416) embedded in the Alpha Control Liner System. The use of the same material for the electrodes for predicate and subject device do not raise any additional questions of safety, as the Alpha Control Liner System has been tested for biocompatibility to ISO 10993-1, 10993-5, and 10993-10. The predicate, Complete Control System Gen2 does not include a liner. The liner material of the Alpha Control Liner System does not raise any additional questions of safety, as the Alpha Control Liner System has been tested for biocompatibility to ISO 10993-1, 10993-5, and 10993-10.

The subject, Alpha Control Liner System is intended to be used with the Complete Control System Gen2. Therefore, the Alpha Control Liner System will use the same software tool, the Complete ControlRoom. The use of the same software tool does not raise any questions of safety and effectiveness as the Alpha Control Liner System has passed validation testing showing compatibility with the Complete Control System Gen2 and Complete ControlRoom software.

Both the subject device, Alpha Control Liner System, and predicate device, Complete Control System Gen2, underwent electrical safety testing for IEC 60601-1. Both devices received passing results. Additionally, the predicate device, Complete Control System Gen2, underwent electromagnetic compatibility testing in accordance with IEC 60601-1-2, CISPR 11, and FCC Part 15. These standards are not applicable to the subject device, Alpha Control Liner System, as it does not contain any wireless capabilities.

The predicate device, Complete Control System Gen2, does not come into contact with the user. Therefore, evaluation to the standard ISO 10993-1 for biocompatibility resulted in no tests being applicable. The subject device, Alpha Control Liner, comes into contact with healthy skin of the user. Therefore, evaluation to the standard ISO 10993-1 for biocompatibility resulted in testing to ISO 10993-5 for cytotoxicity, ISO 10993-10 for skin irritation, and ISO 10993-10 for sensitization. The Alpha Control Liner System received passing results for all three biocompatibility tests.

The subject device provides muscle contraction signals similar to the EMG Interface Cable of the predicate device. As with the predicate the subject device does not include prosthetic limbs.

## 8. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the Alpha Control Liner System and in showing substantial equivalence to the predicate device that is subject to this Special 510(k) submission, Coapt LLC and WillowWood Global LLC completed a number of non-clinical performance tests. The Alpha Control Liner 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 Alpha Control Liner 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
- Cytotoxicity testing per ISO 10993-5
- Skin irritation testing per ISO 10993-10
- Sensitization testing per ISO 10993-10

The Alpha Control Liner System 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 |
|---|---|
| Liner Thickness | Pass |
| Liner Doffing Force | Pass |
| Donning/Doffing Fatigue | Pass |
| Liner Umbrella Static Loading | Pass |
| Liner Umbrella Fatigue Loading | Pass |
| Lead Impedance Fatigue | Pass |
| Lead Impedance - Corrosion | Pass |
| Lock Body Static Loading | Pass |
| Lock Body Fatigue Loading | Pass |
| Liner High Pot Test | Pass |
| Module High Pot Test | Pass |
| Module Level Test | Pass |
| Coapt System Integration Testing | Pass |

## 9. 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.

## 10. 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 Alpha Control Liner System 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 Alpha Control liner System has received passing results for safety testing for electrical safety, ingress protection, and mechanical strength; passing results for performance and usability testing for cabling connection, power on and boot, inputs, and outputs; and validation testing with compatible prosthetic devices.

The Alpha Control Liner System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.