December 30, 2022

Coapt
Kevin Dwyer
Regulatory Compliance & Legal Affairs Manager
303 W. Institute Pl.
Suite 200
Chicago, Illinois 60610

Re: K223605
Trade/Device Name: ControlSeal Electrode (ELSB)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 1, 2022
Received: December 2, 2022

Dear Kevin Dwyer:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team, Acute Injury Devices Team
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)*
K223605

Device Name
ControlSeal Electrode (ELSB)

Indications for Use *(Describe)*
The ControlSeal Electrodes are intended for non-invasive use with recording and monitoring equipment of Electromyography (EMG).

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 – ControlSeal Electrode

1. Submitter Information

Manufacturer:	Coapt, LLC 303 W. Institute Pl. Suite 200 Chicago, IL 60610
Contact Person:	Kevin Dwyer Regulatory Compliance & Legal Affairs Manager
Contact Information:	(844)262-7800 x716 kevin.dwyer@coaptengineering.com
Date Prepared:	12/01/2022

2. Device Identification

Trade/Proprietary Name:	ControlSeal Electrode
Common/Usual Name:	Cutaneous Electrode
Classification Name:	Electrode, cutaneous
Regulation Number:	21 CFR §882.1320
Product Code:	GXY, Cutaneous electrode
Device Class:	Class II
Classification Panel:	Neurology

3. Legally Marketed Predicate Device

510(k) Number	Device Name
K190416	Dome Electrodes

4. Device Description

The ControlSeal Electrode is an accessory designed for recording of biopotential signals. It is a non-invasive electrode that records biopotential signals from the surface of the skin. It has a standard mating thread that enables connection to electrical conductors of compatible devices.

The ControlSeal Electrode contains the following components:

- 316L Stainless Steel ControlSeal Electrode Dome
- Passivated 18-8 Stainless Steel Phillips Flat Head 2-56 Screw
- Stainless Steel Tooth Lock Washer
- Protective Cap
- Conducting Ring-Terminal
- Buna-N Rubber O-Ring

5. Indication for Use Statement

The ControlSeal Electrodes are intended for non-invasive use with recording and monitoring equipment of Electromyography (EMG).

6. Comparison to Predicate Devices

The following table compares the ControlSeal Electrode to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials used, performance, and safety/performance testing. The subject device does not raise any new issues of safety or efficacy based on the similarities to the predicate device.

Manufacturer:	**Coapt, LLC**	**Coapt, LLC**	**Device Comparison**
Trade Name:	**ControlSeal Electrode**	**Dome Electrode**	
510(k) Number	TBD	K190416	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

Indications for Use	The ControlSeal Electrodes are intended for non-invasive use with recording and monitoring equipment of Electromyography (EMG).	The Dome Electrodes are intended for non-invasive use with recording and monitoring equipment of Electromyography (EMG).	Same
Use/Field of Application	The Coapt ControlSeal Electrodes are compatible with most of the EMG equipment that are used in the world.	The Coapt Dome Electrodes are compatible with most of the EMG equipment that are used in the world.	Same
Mechanism of Action	Non-invasive transfer of biopotential signals	Non-invasive transfer of biopotential signals	Same
Electrode Dimensions	Diameter – 9.906 mm Surface Area – 2.73 cm^2	Diameter – 9.525 mm Surface Area – 2.80 cm^2	Similar
Electrode Contact Material	316L Stainless Steel	316L Stainless Steel	Same
Electrode resistivity as a % of typical skin impedance	3.57 x 10^{-12}%	3.57 x 10^{-12}%	Same
Electrode Connection Thread	Common thread stud	Common thread stud	Similar. Different standard thread sizes, but achieve the same purpose.
Biocompatibility Testing Passed	See ControlSeal ISO 10993 Biocompatibility Discussion	ISO 10993-5: Cytotoxicity ISO 10993-10: Sensitization ISO 10993-10: Irritation	Similar

Both the ControlSeal Electrode and the predicate, Dome Electrode are classified as product code: GXY, cutaneous electrodes under 21 CFR 882.1320. Both devices operate in the same manner – the non-invasive transfer of biopotential signals.

The intended use of the predicate Dome Electrode is for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG). The intended use of the ControlSeal Electrode the same - for non-invasive use with recording and monitoring equipment of Electromyography (EMG). This does not raise any concerns of safety or effectiveness. The ControlSeal Electrode and predicate Dome Electrode are both recording the electrical potentials passively. Both the ControlSeal Electrode and Dome Electrode are able to detect these biopotential signals because they create an equipotential surface that conduct the electrical potentials.

The use/field of application for the ControlSeal Electrode and predicate are the same. Both the ControlSeal Electrode and the predicate record biopotential signals from cutaneous locations.

The ControlSeal Electrode and predicate device share similar physical dimensions and shape. They both have a diameter between 9 and 10mm. Both the ControlSeal Electrode and Dome Electrode share a semi-spherical shape for the contacting surface of the electrodes. The difference in surface area of the contacting surfaces of the ControlSeal Electrode and predicate do not cause any concerns of safety. The ControlSeal Electrode has also passed performance testing demonstrating the ability to detect quality EMG signals from cutaneous locations on a user.

The ControlSeal Electrode contacting surface is made from 316L Stainless Steel. The material of the contacting surface for the predicate Dome Electrode is also made from 316L Stainless Steel. The goal in designing the ControlSeal Electrodes was to create a surface electrode for recording EMG signals that was reusable, biocompatible, and cost effective. The ControlSeal Electrodes underwent performance testing to assess the conductivity of EMG signals. The ControlSeal Electrodes passed all performance testing for EMG signal detection. Additionally, the predicate device, Dome Electrode was tested for conformance to the biocompatibility specifications of ISO 10993-5 for cytotoxicity, ISO 10993-10 for skin sensitization, and ISO 10993-10 for irritation. Following the Biocompatibility Risk Analysis, no additional testing is required to evaluate the biocompatibility of the ControlSeal Electrodes. The history of safe use of 316L Stainless Steel in medical devices and comparison to the previously cleared version of the device have resulted in no additional concerns for safety and effectiveness of the ControlSeal Electrode. The intended use, anatomical location, duration, size, material, passivation standard, of the ControlSeal Electrode is the same as the previously cleared device, Dome Electrode. Additionally, there have not been any adverse events in relation to biocompatibility reported for the previously cleared, Dome Electrodes. The 316L Stainless Steel was chosen as the material for the ControlSeal Electrode because it fits the intended application of a reusable, biocompatible, low-cost EMG surface electrode. Also, as discussed in the comparison to uncleared predicate electrodes, stainless steel is widely used in the prosthetic industry.

Because the subject device, ControlSeal Electrode and predicate device, Dome Electrode are made from the same material, they would have the same Electrode resistivity as a % of typical skin impedance. A calculation using the conductivity of the materials, and the average impedance of the skin was performed by comparing the resistivity of gold and 316L Stainless Steel as a percentage of the typical impedance of the skin. The resistance of the skin is about 1000 ohms, making the resistivity of the electrodes 3.57×10^{-12}%.

As with the predicate, the ControlSeal Electrode is designed to operate with a wide range of compatible devices. The ControlSeal Electrode can be connected to compatible devices through a standard sized threaded stud. It is not permanently connected to any electrode leads. The predicate device, Dome Electrodes use a 4-40 standard sized thread, and the subject device, ControlSeal Electrode uses a 2-56 standard sized thread. The differences in electrode connection do not raise any concerns of safety or effectiveness of the ControlSeal Electrode, they are simply alternative means of connection to compatible devices. The method of connection of the ControlSeal Electrode does not have an effect on its ability to detect EMG

signals. The ControlSeal Electrodes have passed performance testing for detection of EMG signals.

7. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the ControlSeal Electrode, substantial equivalence to the predicate device, and in showing conformance to the recognized consensus standard IEEE 2010-2012 Recommended Practice for Neurofeedback Systems that are subject to this Special 510(k) submission, Coapt, LLC completed a number of non-clinical performance tests. The ControlSeal Electrode meets all the requirements for overall design, safety, and biocompatibility results, confirming that the design output meets the design inputs and specifications for the device.

The ControlSeal Electrode passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support safety and efficacy of the subject device:

- IEEE 2010-2012 Recommended Practice for Neurofeedback Systems
- ISO 10993-1: 2009/(R)2013 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process

The ControlSeal Electrodes were 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
Mechanical Fit Test	Pass
Voltage Continuity Test	Pass
Signal Detection Test	Pass
Mechanical Strength Test	Pass
Sealing Test	Pass
Validation – Compatible Device – Coapt COMPLETE CONTROL System Gen2	Pass
Validation – Compatible Device – Coapt Evaluation Kit	Pass

8. Clinical Performance Data

No human clinical testing was required to support the medical device as it was designed to conform to IEEE 2010-2012 Recommended Practice for Neurofeedback Systems. Cutaneous electrodes have been on the market for many years with proven safety and efficacy. The non-clinical testing detailed in

this submission supports the supports substantial safety and efficacy when used for its intended purposes.

9. Statement of Substantial Equivalence to Predicate Device

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 technological characteristics between the ControlSeal Electrode 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 ControlSeal Electrodes have received passing results for performance testing of mechanical fit, voltage continuity, signal detection, sealing, and validation testing with compatible devices.

The ControlSeal Electrode, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.