June 26, 2026

Jason Ford
Regulatory Affairs Manager
Cadwell Industries, Inc.
909 N Kellogg St.
Kennewick, Washington 99336

Re: K261442
Trade/Device Name: Charlotte ACC25 Surface Electrode Array; Charlotte ACC25 Reusable Surface Electrode Array
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 30, 2026
Received: April 30, 2026

Dear Jason Ford:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Digitally signed by MARY S. KESZLER -S
Date: 2026.06.26 09:04:39 -04'00'

For Tushar Bansal
Acting Assistant 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261442

Please provide the device trade name(s).

Charlotte ACC25 Surface Electrode Array;
Charlotte ACC25 Reusable Surface Electrode Array

Please provide your Indications for Use below.

Charlotte Surface Electrode Arrays are indicated for non-invasive use with recording and monitoring equipment to acquire physiological electrical signals from Electromyography (EMG), Electroencephalograph (EEG), and Evoked Potentials (EP).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Electrode Array 510(k) Summary
K261442

Submitter Information

Submitter Name:	Cadwell Industries, Inc. 909 N. Kellogg Street Kennewick, Washington 99336
Submitter Phone:	509-735-6481
Contact Person:	Jason Ford Regulatory Affairs Manager
Date Summary Prepared:	June 25, 2026

Subject Device

Trade Name:	Charlotte ACC25 Surface Electrode Array; Charlotte ACC25 Reusable Surface Electrode Array
Common Name:	Cutaneous Electrode
Classification Name:	21 CFR section 882.1320
Product Code:	GXY

Predicate Device

510(k) Number:	K072016
Trade Name:	Cutaneous Electrodes
Submitter Name:	Technomed Europe
Classification Name:	Neurology 21 CFR 882.1320
Product Code:	GXY

Device Description

Charlotte Surface Electrode Arrays consist of an assembly of surface electrodes terminated to one or more connectors or printed circuit boards. The arrays are intended to record the indicated monitored physiological signals in a non-invasive manner. The electrodes are provided non-sterile. Optionally, Surface Electrode Arrays may be affixed to a proprietary carrier intended to facilitate a Surface Electrode Array's connection with separately FDA-cleared compatible recording devices.

The device is intended to be used with FDA-cleared electrode conductive paste.

Available as Single-use disposable assemblies, or reusable assemblies.

Indications for Use

Charlotte Surface Electrode Arrays are indicated for non-invasive use with recording and monitoring equipment to acquire physiological electrical signals from Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials (EP).

Summary of Technological Characteristics and Comparison to the predicate devices

Table 1

Characteristics	***Subject Device*** ***Charlotte ACC25 Surface Electrode Array; CharlotteACC25 Reusable Surface Electrode Array (K261442)***	***Predicate Device*** ***Technomed Cutaneous Electrodes*** ***(K072016)***	***Discussion of Major Differences***
Device Class	Class II	Class II	No differences
Class Name	Cutaneous Electrode	Cutaneous Electrode	No differences
Product Code	GXY = Electrode, Cutaneous	GXY = Electrode, Cutaneous	No differences
Regulation	882.1320	882.1320	
Intended User	Medical Professional	Medical Professional	No differences
Target Patient Population	Adults and Pediatric	Adults and Pediatric	No differences
Prescription	Prescription use only	Prescription use only	No differences
Type of Use	Single Use, Reusable	Single Use, Reusable	No differences
Indications for Use	Charlotte Surface Electrode Arrays are indicated for non-invasive use with recording and monitoring equipment to acquire physiological electrical signals from Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials (EP).	The cup electrodes are intended for non-invasive use with recording and monitoring equipment (active and reference), of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potentials.	No significant differences
Electrode Materials	Disposable: Silver/Silver Chloride (Ag/AgCl); Acrylonitrile Butadiene Styrene (ABS) Reusable: Ag, Ag/AgCl, or Gold (Au)-plated.	Disposable: Ag/AgCl; ABS Reusable: Ag/AgCl, Au-plated	No differences
Electrode Connector	Proprietary connection with latching mating mechanism	DIN 42-802 touch proof connector	These design differences do not introduce new questions of safety or effectiveness
Safety and Performance Characteristics	Same	Same	This submission uses the Safety and Performance Based Pathway; therefore a direct comparison of the safety and performance characteristics is not required.

Performance Data

In accordance with the FDA guidance document, "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*", issued on August 14, 2020, the following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination.

Electrode Characterization:

• Electrical Performance per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*

- o AC Impedance
- o Offset Voltage
- o Combined offset instability and internal noise
- o Bias Current Voltage (DC Voltage Offset)

Sufficient justification was provided to ensure the device characteristics of shelf life and conductive connection compliance considerations under the Cutaneous Electrodes guidance did not impact the safety and effectiveness of the subject device.

Biocompatibility

The biocompatibility of the subject device is based upon verified claims of identical materials of construction compared to the predicate devices, as well as on the use of skin-contacting, low biocompatibility risk materials with a long history of safe use in accordance with Attachment G of the FDA's 2023 Biocompatibility Guidance.

Summary of Non-clinical Testing

Safety and Performance bench testing of Charlotte Surface Electrode Arrays that confirm the claimed performance characteristics of the subject device. The results of the completed evaluations and testing demonstrate that any differences relative to the predicate device do not raise different questions of safety and effectiveness. Therefore, the performance data demonstrate acceptable safety and performance compared to the predicate devices.

Conclusion

The Charlotte ACC25 Surface Electrode Arrays have the same intended use as the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the performance data demonstrate that the Charlotte ACC25 Surface Electrode Arrays are substantially equivalent to the cleared predicate device.