K962457

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Section 2 - Summary and Certification

December 20, 1996

A. 510(k) Summary of Safety and Effectiveness

The proposed device consists of the existing two-channel preamplifier and a buffered electrode input box with extension cable. These components provide electrode inputs that are closer to the source of the signal during electromyographic (EMG) testing. The intent of this design is to reduce signal noise during procedures requiring high-impedance electrodes. The proposed device is for use with the Cadwell Sierra (K924723) and 6200A (K931428) EMG instruments.

All device components are reusable and supplied non-sterile. The extension cable with electrode input box is compatible with EtO sterilization guidelines for procedures requiring a sterile field. The input box is available with separate active and reference input connectors or a single phono jack connector.

The attached extension cable connects the input box to the preamplifier by way of a cable adapter. The existing preamplifier will be fitted with three pin DIN connectors to accept the cable adapter.

1. Submitter Name and Identification

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Contact: Chris Bolkan
Establishment Registration Number: 3020018

2. Proposed Device Name and Part Number

Trade Name (Proprietary Name): Cadwell Sierra and 6200A

Proposed Device	Order Number
Two-Channel Preamplifier	190152-200
Buffered Input Box with Extension Cable	197112-200
Cable Adapter	199155-200

Common Name or Usual Name: Electromyography and Evoked Potential Equipment.

Classification: Type II

Name	Number
Electromyograph	84GWP
Electromyograph, Diagnostic	89IKN

3. **Identification of the Substantially Equivalent Device**

Reason for Premarket Notification: Modification to an existing device.

Modification of Existing Device: The proposed device is a modification to the existing Cadwell Sierra (K924723) and 6200A (K931428) devices. The Cadwell two-channel preamplifier with buffered input box allows electrode inputs to be made closer to the signal source for reduced noise during procedures requiring high-impedance electrodes. The proposed device complies with the same safety standards as the existing devices.

Safety of the Cadwell Sierra (K924723) and 6200A (K931428) Devices

The original device complies with the following safety standards for medical equipment:

IEC 601-1 Medical Electrical Equipment. Part 1. General requirements for safety. Type: Class 1 or grounded equipment, continuous operation, with B and BF applied parts.

IEC 878 (1988) Graphic symbols for electrical equipment in medical practice.

NFPA 99. Standard for Health Care Facilities.

The original device complies with the following general safety standards for electrical equipment:

ANSI/NFPA No. 70 (1990) National electric code.

UL 796 Standard for printed wiring boards.

UL 94 Standard for tests for flammability of plastic materials for parts in devices and appliances.

Safety of the Cadwell Sierra (K924723) and 6200A (K931428) Two-Channel Preamplifier Device

The original device complies with the following standards:

IEC 601-1 isolated applied part Type BF.

American Electroencephalographic Society Guidelines for Clinical Evoked Potential Studies, 1984. Section III. Standards for Clinical Evoked Potential Equipment: Minimal Standards, Amplifier Averager. Section IV. Standards for Clinical Evoked Potential Recording: Calibration.

Effectiveness of the Cadwell Sierra (K924723) and 6200A (K931428) Devices

The original device is designed to perform the measurements needed for electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), evoked potentials (brainstem, visual, somatosensory) and repetitive nerve stimulation. The effectiveness of these clinical protocols is described in standard medical school textbooks. Please refer to the following texts for additional information.

Aminoff MJ: *Electrodiagnosis in Clinical Neurology*, Churchill Livingstone Inc., 1980.

Chiappa KH: *Evoked Potentials in Clinical Medicine*, ed 2. Raven Press, 1990.

Delisa JA: *Manual of Nerve Conduction Velocity and Somatosensory Evoked Potentials*, ed 2. Raven Press, 1987.

Johnson EW: *Practical Electromyography*, ed 2, Williams & Wilkins, 1988.

Kimura J: *Electrodiagnosis in Diseases of Nerve and Muscle: Principles and Practice*, ed 2. A Davis Company, 1989.

Spehlmann R: *Evoked Potential Primer: Visual, Auditory, and Somatosensory Evoked Potentials in Clinical Diagnosis*, Butterworth Publishers, 1985.

Regan D: *Human Brain Electrophysiology: Evoked Potentials and Evoked Magnetic Fields in Science and Medicine*. Elsevier Science Publishing Co., Inc., 1989.

4. Description of the Proposed Device

The extension cable with buffered electrode input box allows electrode inputs to be made closer to the source of the signal for reduced signal noise during procedures requiring high-impedance electrodes. The electrode input box is available with separate active (labeled •) and reference connectors or a single phono jack connector to accommodate recording electrodes with these connector types.

The input box is enclosed in a white polyethylene foam sheath. The sheath houses a circuit board consisting of a buffer circuit, two electrostatic discharge (ESD) networks (one on each side of the buffer circuit), and a separate circuit designed to limit fault currents.

The circuit board is attached to a polyvinyl chloride extension cable terminated in an eight-pin DIN connector. The input box and extension cable are connected to the preamplifier by way of a polyvinyl chloride cable adapter terminated in a three-pin DIN connector. The adapter cable does not qualify as a class II device.

5. Statement of Intended Use

The general purpose of the proposed device is identical to the predicate device: "to perform the measurements needed for electromyography (EMG), nerve conduction velocity (NCV, F wave, and H reflex), and evoked potentials (brainstem, visual, and somatosensory), and repetitive nerve stimulation." The purpose of the proposed device is to allow compatibility with high-impedance electrodes. The proposed device allows electrode inputs to be made closer to the source of the signal for reduced signal noise during procedures requiring high-impedance electrodes.

Duration of Use

The two-channel preamplifier with buffered input box is designed for use during the duration of the procedure only. This device is not for chronic use and is labeled accordingly.

Intended Use Environment

Use of the proposed device is to be administered under the direction of a trained physician, surgeon, neurologist, or electrophysiologist in a suitable operating room or clinic.

6. Comparison of Device Technological Characteristics

The proposed device is a modification to the Sierra (K924723) and 6200A (K931428) preamplifier devices. Physical modifications to the predicate device are in the following areas:

1. The recording component (electrode input box) from the existing preamplifier is mounted at the end of the extension cable. The proposed device provides closer electrode inputs for reduced signal noise during procedures requiring high-impedance electrodes.
2. The proposed input box and extension cable are compatible with EtO sterilization requirements.
3. To accommodate the proposed input box and extension cable, the existing preamplifier requires a hardware upgrade from the existing five-pin DIN connector to a three-pin DIN connector. The proposed device also requires a preamplifier cable adapter. The cable adapter does not qualify as a class II device.

The proposed device and the predicate device have nearly identical technical specifications and characteristics. The modification consists of adding a remote electrode input box for use with a single, high-impedance electrode. The input box connects to the existing preamplifier by way of an extension cable and cable adapter. The cable adapter requires a three-pin DIN connector in place of the standard five-pin DIN connector currently on the preamplifier.

Criteria	***Cadwell Sierra and 6200A with the existing two-channel preamplifier***	***Cadwell Sierra and 6200A with the proposed two-channel preamplifier and buffered input box***
Safety	Designed to comply with requirements of UL 544. Classification: isolated patient connections IEC 601-1: Type BF.	Designed to comply with requirements of UL 544. Classification: isolated patient connections IEC 601-1: Type BF.
Electrode inputs	Two buffered electrode inputs with separate active and reference 1.5-mm touch-proof connectors or 5-pin DIN connector.	• Two buffered electrode inputs with separate active reference 1.5-mm touch-proof connectors. • One remote buffered electrode input for separate active and reference pin jack connectors or single phono jack connector. Preamplifier fitted with 3-pin DIN connector
Isolated ground connections	1 connection	1 connection
Isolation mode rejection	> 150 dB.	> 150 dB.
Common mode rejection	> 100 dB	> 100 dB.
Sensitivities	2, 5, 10, 20, 50, 100, 200, 500 micro V/div; 1, 2, 5, 10, 20 m V/div.	2, 5, 10, 20, 50, 100, 200, 500 micro V/div; 1, 2, 5, 10, 20 m V/div.
Noise	2 micro V peak to peak (10 Hz to 10 kHz).	2 micro V peak to peak (10 Hz to 10 kHz).
Input impedance	> 1,000 Mohms (common mode)	> 1,000 Mohms (common mode)
Notch filter	50 or 60 Hz	50 or 60 Hz
Low-cut filters	1- or 2-pole filter. Selectable at 0.04, 0.1, 1, 3, 10, 30, 100, 500 Hz.	1- or 2-pole filter. Selectable at 0.04, 0.1, 1, 3, 10, 30, 100, 500 Hz.
High-cut filters	2-pole (12 dB/octave) filter. Selectable at 30, 50, 100, 200, 300, 500 Hz; 1, 1.5, 2, 3, 5, 10, 15 kHz.	2-pole (12 dB/octave) filter. Selectable at 30, 50, 100, 200, 300, 500 Hz; 1, 1.5, 2, 3, 5, 10, 15 kHz.
Temperature probe input	20 to 45 °C	20 to 45 °C

Testing and Validation

The proposed device underwent engineering and clinical testing to validate that the device functions as a remote buffer preamplifier when used with the appropriate electrodiagnostic device. For validation procedures and results, please see Enclosure 3 of the previous submission dated October 16, 1996.

Conclusion

The results of engineering tests 1 and 2 indicate that the input impedance is greater than 10 Mohms when the active and reference connectors are subjected to ten strikes of 8-kV ESD each.

The following tests were carried out with the proposed device connected to the intended electrodiagnostic instrument. The results from test 3 show that the gain is not affected by passing the signal through the proposed device. The results from test 4 show that the patient auxiliary current is well below the regulatory limits set forth by IEC 601-1 for BF connections. The results from test 5 show that the measured value of peak-to-peak noise is less than the allowed valued.

Clinical results from test 6 show that the proposed device does not distort the morphology of the nerve conduction waveform, nor does it significantly affect the onset time, peak time, or amplitude when compared to the signal that does not pass through the proposed device. Additional clinical results in test 7 indicate that the proposed device does not distort the morphology of the EMG waveform when compared to the signal that does not pass through the proposed device.