

JUN 22 1993

h931428

**This document is a summary of the safety and effectiveness of the 6200A device.**

**Safety of the Cadwell 6200A.**

The specifications for the safety of the instrument are listed in the Operators Manual under the 6200A specifications.

**Effectiveness:**

The Cadwell 6200A is designed to perform the measurements needed for Electromyography (EMG), Nerve Conduction Velocity (NCV, F wave, H wave), Evoked Potentials (Brain Stem, Visual, Somatosensory) and Repetitive Nerve Stimulation. The effectiveness of these clinical protocols is described in standard medical school text books. Please refer to the following texts for further information.

Joel A. Delisa, 1987, Manual of Nerve Conduction Velocity and Somatosensory Evoked Potentials (Second Edition), Raven Press.

Jun Kimura, 1989, Electrodiagnosis in Diseases of Nerve and Muscle: Principles and Practice (Second Edition), F. A. Davis Company.

Ernest W. Johnson, 1988, Practical Electromyography (Second Edition), Williams and Wilkins.

Keith H. Chiappa, 1990, Evoked Potentials in Clinical Medicine (Second Edition), Raven Press.

Michael J. Aminoff, 1980, Electrodiagnosis in Clinical Neurology, Churchill Livingstone Inc.

Rainer Spehlmann, 1985, Evoked Potential Primer. Visual, Auditory, And Somatosensory Evoked Potentials in Clinical Diagnosis, Butterworth Publishers.

David Regan, 1989, Human brain Electrophysiology. Evoked Potentials and Evoked Magnetic Fields in Science and Medicine, Elsevier Science Publishing Co., Inc.



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Food and Drug Administration  
1390 Piccard Drive  
Rockville, MD 20850

Garlton M. Cadwell, D.D.S.  
President  
Cadwell Laboratories, Inc.  
909 North Kellogg Street  
Kennewick, Washington 99336

Re: K931428  
Cadwell 6200 A  
Regulatory Class: II  
Dated: March 19, 1993  
Received: March 22, 1993

Dear Mr. Cadwell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Device Labeling Compliance Branch (HFZ-326) at (301) 427-1342. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health