

K960170

510(k) Summary

- **Submitter's Information:** Moberg Medical, Inc.
124 S. Maple Way
Ambler, PA 19002
Phone: 215 283-0860
Fax: 215 283-0859
- **Contact:** Larry Engle
- **Date:** 1-15-96
- **Trade name:** Neurotrac II-EP
- **Common name:** Neurotrac II-EP
- **Classification name:** Electroencephalograph (EEG)
EEG Signal Spectrum Analyzer
Evoked Response Electrical Stimulator
Evoked Response Auditory Stimulator
- **Substantially Equivalent Predicate Devices:**

Product	Manufacturer	510(k) No.	Comments
Neurotrac II	Moberg Medical, Inc. 124 S. Maple Way Ambler, PA 19002	K914571A	Basic foundation for Neurotrac II-EP
Viking IV	Nicolet Biomedical Inc. 5225 Verona Rd. Madison, WI 53711	**	Configured with Intra-Operative Monitoring Software Package-IOM
Excel	Cadwell Laboratories, Inc. 909 N. Kellogg St. Kennewick, WA 99336	**	One of many Models for EP/EEG carried by Cadwell.
Neuropack 8	Nihon Kohden America Inc. 2601 Campus Dr. Irvine, CA 92715	K851300	8-channel version of Neuropack product line which includes Neuropack 2, Neuropack 4 Mini

** 510(k)'s not available from FOI. Equivalence based on labeling (See appendix B) and information available from ECRI Healthcare Product Comparison System, #217982:424-008, March 1995. Plymouth Meeting, PA 19462-1298.

510(k) Summary

• Device Description:

The Neurotrac II-EP provides continuous monitoring of brain electrical activity (EEG) and monitoring of evoked electrical activity from the central and peripheral nervous system (EP). The system provides for recording of any combination of EEG/EP and displays the results. The system not only displays the raw EEG waveform but processes the EEG in ways which make it easier to detect changes in the amplitude and frequency of the signal. The amplitude and frequency of the signal are the two main characteristics of the EEG. In addition to displaying the EEG, the raw input of the EP waveform as well as its average are displayed. The system processes the EP waveform which makes it easier to detect changes in the amplitude and latency of the signal. The amplitude and latency of the signal are the two main characteristics of the EP. The Neurotrac II-EP also provides clinicians the capability of reviewing collected data. All raw EEG and EP waveforms and computer processed information may be stored on an internal hard drive or a removable cartridge hard drive for retrieval at a later time. All data can be printed for immediate hard copy interpretation.

The Neurotrac II-EP

Moberg Medical, Inc. (MMI) designs and manufactures the Neurotrac II monitor (510k# K914571A). The Neurotrac II monitors brain function via the electroencephalogram (EEG). The new Neurotrac II-EP is an enhanced version of the original Neurotrac II. The Neurotrac II-EP monitors brain function via the electroencephalogram (EEG) and via evoked potentials (EP). Although, the Neurotrac II-EP will expand the features and functions of the Neurotrac II platform the intended uses are the same as the predicate devices. The Neurotrac II-EP is designed and manufactured by MMI. No changes in the product enhancement are being made which will adversely affect patient safety.

The Neurotrac II-EP System

The product will be sold as Neurotrac II-EP configured with hardware and software for both continuous EEG, auditory and somatosensory evoked potential monitoring. The amplifiers, processor unit and evoked potential stimulator of the Neurotrac II-EP system will be manufactured by Moberg Medical. These components are connected to the M1094 Display, manufactured by Hewlett-Packard (HP), to complete the basic Neurotrac II-EP system. The amplifiers are housed in a connecting box (headbox) which accepts one of several patented "Personality Cards (PCARD)". The electrode leadwires connect into the PCARD which shows the user where to connect the patient electrodes on the head and configures user defined monitoring procedures for different clinical applications. The PCARD only accepts electrodes with DIN 42 802 standard touch proof connectors. The evoked potential stimulator includes both auditory and electrical outputs. These are delivered to the patient by industry standard auditory headphones or tube phones and FDA approved electrodes for electrical stimulation. The electrical stimulator provides for six standard current level outputs and two low current level outputs. The low current level outputs are designed to be used with custom electrodes, provided with the Neurotrac II-EP. These custom electrodes provide for additional patient safety by prohibiting their use in standard higher current level outputs. A keyboard and mouse are provided for entry of alpha numeric information and changes with pull-down menus for parameters. Accessories to the product are a computer cart for portability, an audio-output for listening to electrical impulses from selected nerves or muscles, a manual switch box to select electrical outputs, a safety agency approved external storage device (i.e. hard drive, optical) and a PCL5 compatible printer for hard copy printouts.

510(k) Summary

The HP Display, Model M1094 provides the electrical power for the MMI processor, amplifiers, evoked potential stimulator and audio speaker.

The Neurotrac II-EP system will be sold by MMI.

- **Intended Use:**

The intended use for the Neurotrac II-EP is:

To record the electroencephalogram (EEG) and evoked potentials (EP's) over extended periods of time such as during surgery and intensive care stays in order for trained health care professionals to observe changes.

The intended use of the Neurotrac II-EP is to monitor the electroencephalogram (EEG) and evoked potentials (EP's) over extended periods of time such as during surgery and intensive care stays in order to observe changes. The Neurotrac II-EP acts as a patient monitor as it displays EEG waveforms, performs calculations on the data and triggers alarms when user-defined limits are exceeded. In addition, the Neurotrac II-EP is an evoked potential measuring device designed to record and measure the brain stem and the somatosensory pathways in order to evaluate nervous system function. It stores monitored waveforms for retrospective on-screen review or for hard copy interpretation. The Neurotrac II-EP is designed for use on the same clinical patient populations as the predicate devices, the Nicolet Viking IV, the Cadwell Excel, and the Nihon Kohdon Neuropack 8. The Neurotrac II-EP is not life supporting nor life sustaining and is used alongside conventional patient monitoring such as ECG and blood pressure.

- **Summary of technological characteristics compared to predicate device:**

In general, the Neurotrac II-EP and the predicate devices are similar in features and technical characteristics. There are no major differences that would alter intended use or jeopardize patient safety. The specifications for diagnostic EMG have not been included here given that the Neurotrac II-EP makes no claim to be a diagnostic EMG product

The indications for use of the Moberg Medical Neurotrac II-EP are the same as those of the predicate devices.

Use of the Neurotrac II-EP is indicated when electroencephalographic (EEG) and/or evoked potential (EP) monitoring is required during surgery or intensive care over extended periods of time. It is necessary for the Neurotrac II-EP to perform a wide variety of EEG techniques and EP modalities for use in these settings. The Neurotrac II-EP is designed as a bedside continuous EEG/EP monitor. The users of the Neurotrac II-EP will be medical professionals who have been trained in patient monitoring procedures.

510(k) Summary

It is necessary for the Neurotrac II-EP, along with the predicate devices, the Neurotrac II, the Viking IV, the Excel and the Neuropack 8 to perform a wide variety of EEG techniques and/or EP modalities. These techniques and modalities differ for ICU and OR neuromonitoring, as compared to the requirements generally found on EEG or EP products in the diagnostic laboratory setting. The EEG functionality of the Neurotrac II-EP is identical to the predicate device the Neurotrac II. The other predicate devices do not have the features and capabilities as the Neurotrac II-EP for recording EEG and do not claim product classification #84GWQ. They therefore, could not function in a diagnostic setting to record an EEG based on the minimal EEG recording standards as set forth by the American EEG Society. Similarly, the predicate devices claim product classification #89IKM, electromyograph, diagnostic. The Neurotrac II-EP is not being marketed for diagnostic EMG recordings. Two of the most common modalities of evoked potentials for OR and ICU work are the brain stem auditory and the short latency somatosensory evoked potential. The Neurotrac II-EP as well as the EP predicate devices the Viking IV, the Excel and the Neuropack 8 allow for a full range of features to perform these modalities. The Neurotrac II-EP as well as the EP predicate devices supports external triggers for pattern reversal stimulation and LED goggle stimulation for recording visual evoked potentials.