BIOMAGNETIC TECHNOLOGIES
9727 Pacific Heights Blvd
San Diego, CA 92121-3721
Tel: 619 453-6300
Fax: 619 453-4913

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510(k) SUMMARY

(a) (1) Submitted By:

Biomagnetic Technologies, Inc. (BTi)
9727 Pacific Heights Blvd.
San Diego, CA 92121

Telephone: (619) 453-6300
Fax: (619) 453-4913

Contact: Eugene C. Hirschkoff, Ph.D.
Director of Clinical Applications

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(2) Name of Device:

Proprietary name: Magnes® II Biomagnetometer
Device trade name: Magnetic Encephalograph

(3) Substantial Equivalence:

The Magnes II Biomagnetometer system is substantially equivalent to the Magnes Biomagnetometer system currently manufactured and marketed by Biomagnetic Technologies, Inc. (Reference 510(k) K901215)

(4) Description of Device:

The Magnes II Biomagnetometer system utilizes superconducting signal pickup coils and Superconducting Quantum Interference Devices (SQUIDs) to detect and amplify magnetic fields produced by electrical activity in the brain. The signals are amplified, filtered and digitized by signal processing electronics. The digitized signals are computer processed to produce displays of information about biomagnetic field strength, direction, and location.

The Magnes II Biomagnetometer system consists of: Two sensor units, one gantry mounted and one floor mounted, which house the superconducting components which are cooled to liquid helium temperature, an electronics subsystem for preliminary analog signal amplification, filtering, and analog-to-digital conversion, a computer subsystem "master analysis processor" to store, process, and display the data, a magnetically shielded room for interference reduction, a patient table for subject/patient support, and a gantry for articulation of the upper sensor.

(5) Intended Uses:

"The Magnes II Biomagnetometer is intended for use in diagnostic procedures that require the measurement and display of extracranial magnetic fields and information about the electrical activity of the brain as inferred from those fields."

(6) Technological Characteristics:

The Magnes II biomagnetometer system provides a second magnetic field sensor unit but is otherwise equivalent to the standard Magnes Biomagnetometer system.

The same electrical currents in the brain that produce electric voltages on the body surface also produce magnetic fields orthogonal to those currents. The magnetic fields are mathematically related to the electrical currents and voltages by the classical electromagnetic field equations of Maxwell, Lenz, and others.

The major technological difference between the Magnes II Biomagnetometer and conventional electrical signal devices (EEG) is the use of superconducting magnetic field sensors. The magnetic field sensor detects and converts magnetic field energy to electrical signals without patient electrical contact. The electronic and computer subsystems are equivalent to processing systems in use by electrical signal devices.

(b) (1) Nonclinical Tests and Results:

Nonclinical tests involve verification of basic physical principles associated with the technology. Typical examples are tests using "phantom" signal sources for localization accuracy, characterization of signal sensitivity, and system background noise relative to biomagnetic signals of interest.

Test results comparing the response of the second Magnes sensor relative to the original Magnes signal sensor indicate that there is no significant difference in the performance of the Magnes II Biomagnetometer system for the detection and display of biomagnetic signals.

(2) Conclusions:

The addition of the second sensor to the Magnes Biomagnetometer system provides additional simultaneous coverage area for signal acquisition and reduction of overall recording time.

Measurement, display, and interpretation of biomagnetic fields originating from electrical activity in the brain has been under development for at least the past 30 years. Current technology has produced enhanced capability through implementation of multiple signal sensors. The Magnes II Biomagnetometer system represents the latest implementation of this technology.

Any questions regarding the 510(k) summary may be directed to the contact person noted.