

K902607

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. General Information.

Establishment:

- Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, N.J. 08830
- Registration Number: 2240869
- Contact Person: Kathleen M. Rutherford
Manager, Regulatory Submissions
(908) 321-4779
- Date of Summary Preparation: July 3, 1996

Device Name:

- Trade Name: Clinical Phosphorus Spectroscopy Option
/ MR System
- Classification Name: Magnetic Resonance Diagnostic
Device, CFR § 892.1000
- Classification: Class II
- Performance Standards: None established under Section
514 of the Food, Drug, and
Cosmetic Act.

II. Safety and Effectiveness Information Supporting the Substantial Equivalence Determination.

Device Description:

The new Clinical Phosphorus Spectroscopy Option for the MAGNETOM VISION consists of hardware/software extensions, a new rf surface coil, and a new quality assurance phantom.

SIEMENS

Intended Use

Siemens developed the Clinical Phosphorus Spectroscopy Option for the Magnetom Vision system to allow the non-invasive in vivo analysis of energy metabolites in muscle, liver and heart tissue. The package allows observation of phosphocreatine (PCr), inorganic phosphate (Pi), Adenosine triphosphate (ATP), phosphomonoester (PME), phosphodiester (PDE) levels. Information provided by phosphorus spectroscopy data allows evaluation of the energetic state of examined tissues and intracellular pH, measured from the chemical shift of Pi.

Technological Characteristics

The MAGNETOM VISION is a magnetic resonance (MR) imaging and spectroscopy system which uses time-varying magnetic field gradients and rf energy to spatially encode the anatomy of a patient. Introduction of the new clinical phosphorus spectroscopy package will not affect the technological characteristics of this system.

General Safety and Effectiveness Concerns:

The Clinical Phosphorus Spectroscopy Option will not affect the safety and imaging performance parameters specified for the MAGNETOM VISION system.

Substantial Equivalence:

The Siemens Clinical Phosphorus Spectroscopy Option is substantially equivalent to the commercially available Proton Spectroscopy Option for the MAGNETOM VISION, and the Spectroscopy Option for the MAGNETOM 63SP.


Signature


Date