K962927

SEP 25 1996

Appendix 8:

510(k) Summary

SIEMENS

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:	Cathy Anne Pinto Sr. Technical Specialist, Regulatory Affairs (908) 321-4887 (908) 321-4841
Date of Summary Preparation:	July 26, 1996

Device Name:

• Trade Name:	In-Room MRC/ MAGNETOM VISION and IMPACT
• 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 Substantial Equivalence.

Device Description:
The In-Room MRC consists of a local monitor and mouse. The local monitor is a liquid crystal display (LCD) with the same image resolution as the standard diagnostic console. The scan-room-mouse is positioned alongside the magnet and controls the functions of the local monitor. It is similar to the conventional track ball-mouse used at the standard MR console and is fully compatible with the software.

Intended Use:
The new In-Room MRC is intended to facilitate conventional procedures. The new operating console allows the system operator to control and monitor main system functions inside the RF-cabin.

Siemens Medical Systems, Inc.
In-Room MRC
186 Wood Ave. South
Iselin, NJ 08830
Tel: (908) 321-4500
Fax: (908) 494-2250

Technological Characteristics:
The local monitor and mouse serve the same function as the standard MR console except that, patient registration must be performed from the standard MR console in the control room via the keyboard.

General Safety and Effectiveness Concerns:
Operation of the new In-Room MRC does not affect any of the MR safety and performance parameters, including:

[safety]
- static field strength,
- RF exposure,
- time varying magnetic fields
- acoustic noise levels

[performance]
- signal-to-noise,
- high contrast spatial resolution,
- slice thickness,
- image uniformity and,
- geometric distortion.

In addition, all new components have been designed and tested for MR compatibility with the system. There is no electrodynamical interference with the static magnetic field, the magnetic field gradients, or the rf system. Consequently, there is no influence on image quality or system performance.

Substantial Equivalence:
The In-Room MRC for the VISION and the IMPACT is substantially equivalent to In-Room MRC commercially available for the MAGNETOM OPEN system.

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Imaging Systems Group
Siemens Medical Systems, Inc.

7/26/96
Date