

JUN 19 1996

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**Appendix 8:
510(k) Summary**

510 (k) SUMMARY

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:** March 20, 1996

Device Name:

- **Trade Name:** Kinematic Knee Device/ OPEN

- **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:

Siemens is introducing a new positioning device that will be used for kinematic MRI studies of the knee. The new positioning device can be used for the left or right knee and is adjustable up to a maximum angle of 100 degrees.

Intended Use

The new kinematic knee device will enable the physician to evaluate the anatomy of the knee and dynamic interaction of the different tissues (ligaments, cartilage, bone, muscle, fat). Such dynamic evaluation may be useful for patellar tracking.

Technological Characteristics

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

The new device accessory is a positioning device which is manually operated by the user. No active components (i.e., motors) are used and there are no ferromagnetic materials that could affect the scan field.

General Safety and Effectiveness Concerns:

The kinematic knee device will not affect the safety and performance parameters specified for the MAGNETOM OPEN system.

Substantial Equivalence:

The Siemens Kinematic Knee Device is substantially equivalent to the commercially available Resonex Kinematic MRI package. The Resonex Kinematic MRI Package was described in K924154 which received FDA premarket clearance on 11/23/92.


Signature

3/20/96
Date