

510 (k) Summary

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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.

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- Date of Summary Preparation: December 22, 1995
- Proprietary Trade Name: Auxiliary Patient Table/
MAGNETOM 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 Substantial Equivalence.

- **Device Description:**
The auxiliary patient table docks into the standard OPEN table area and increases the vertical gap (ie. patient gap) of the magnet. The auxiliary patient table consists of a base frame, an extension frame, and a table plate.

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- **Intended Use**

The auxiliary patient table is designed to further accommodate large patients, trauma patients, claustrophobic patients, and those patients requiring monitoring. The new auxiliary table is designed to support up to 200kg (440 lbs) and is compatible with the commercially available CP Head and Multi-purpose Coils. This new system option is not intended as a transportation trolley.

- **Technological Characteristics**

There is no change to the magnet, rf system, and gradient system of the MAGNETOM OPEN by introduction of the auxiliary patient table.

- **General Safety and Effectiveness Concerns:**

Operation of the MAGNETOM OPEN system with the new auxiliary patient table is substantially equivalent to standard operation of the MAGNETOM OPEN system. The following safety parameter action levels:

- static field strength,
- RF exposure,

and performance levels:

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

specified by the FDA guidance document for MR Diagnostic Devices are unaffected by the modifications described within this notification.

- **Substantial Equivalence:**

The MAGNETOM OPEN with the new auxiliary patient table is substantially equivalent to standard operation of the MAGNETOM OPEN system.


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12/22/95
Date