FEB 2 4 1997

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

K964752

Classification:	Class II
	Magnetic Resonance (MR) Imaging System
Common/Usual Name:	Magnetic Resonance Imaging Accessories
Proprietary Name:	Kinematic Positioning Devices: C-Spine, Knee and Shoulder

Establishment Registration

Manufacturer:	Picker Nordstar, Inc.
	P.O. Box 33
	FIN-00511 Helsinki, FINLAND
	Phone: +358-9-394 127
	Fax: +358-9-146 2811
	FDA Facility Registration #9680194
United States Representative:	Picker International, Inc.
	595 Miner Road
	Cleveland, OH 44143
	FDA Owner Number #1580240
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The Picker International Outlook system is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

The Kinematic Positioning Devices enable the physician to evaluate the anatomy and the functional interactions of the surrounding tissues (ligaments, cartilage, bone, muscle and fat). The Kinematic Positioning Devices are indicated for use in the Cervical Spine, Knee and Shoulder.

3. Device Description

C-Spine Positioning Device

The Outlook C-spine positioning device is designed to keep the head of the patient constrained in different positions while the C-spine is being imaged in the Outlook scanner. The device allows flexion, extension, lateral movement and lateral rotation. There is also a possibility to set the distance between the horizontal (flexion/extension) axis and the vertical axis (lateral motion). The device has an integrated holder for the Multipurpose receiver coil.

Knee Positioning Device

The Outlook Knee positioning device is designed to keep the leg constrained in different positions while the knee joint is imaged in the Outlook system with a Multipurpose coil. The device is used for flexion and extension of the knee.

Shoulder Positioning Device

The Outlook Knee positioning device is designed to keep the arm of the patient constrained in different positions while the shoulder joint is being imaged in the Outlook scanner. The device allows abduction, adduction and internal/external rotation. The device has an integrated holder for the Multipurpose receiver coil.

4. Safety and Effectiveness

The Picker International Kinematic Positioning Devices for the Outlook are similar in technological characteristics and intended use to the Siemen's Kinematic Knee Device for the Magnetom Open System (K961121). The following chart has been created to demonstrate their substantial equivalence.

SUBSTANTIAL EQUIVALENCE CHART

Parameter	Kinematic Positioning Devices for the Outlook	Predicate Device Kinematic Knee Device for the Magnetom Open System (K961121)
Material	Same	No ferromagnetic materials which could affect the scan field.
Device operation	Same	Manually operated by the user. No active components such as motors.
Indications for Use	C-Spine, Knee, Shoulder scanning	Knee scanning
Intended use	The **Siemens Magnetom Open** is a magnetic resonance imaging system which uses time-varying magnetic field gradients and rf energy to spatially encode the anatomy of the patient. The 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). The **Picker International Outlook system** is intended for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon NMR parameters (proton density, flow velocity, spin-lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis. The Kinematic Positioning Devices enable the physician to evaluate the anatomy and the functional interactions of the surrounding tissues (ligaments, cartilage, bone, muscle and fat)	