

K960973

SUMMARY OF SAFETY AND EFFECTIVENESS

1. General Information.

MAY 29 1996

Classification: Class II  
Magnetic Resonance (MR) Imaging System

Common/Usual Name: MRI Patient Couch

Proprietary Name: Movable Add-on Couch for Outlook

Establishment Registration: Manufacturer:  
Picker Nordstar, Inc.  
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FIN-0051 Helsinki, FINLAND  
Phone: +358-0-394 127  
Fax: +358-0-146 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. The device and its labeling comply with the following applicable requirements.

Code of Federal Regulations Title 21, Subchapter J - Radiological Health, applicable sections which include:

1020.30(c)	Certification of components
1020.30(e)	Identification of X-ray components
1020.30(g)	Information for assemblers
1020.30(h)	Information for users
1020.30(n)	Aluminum equivalent of material
1020.31(3)(1)(i)	Beam axis perpendicularity to image receptor and SID

**2. Intended Uses**

The Movable Add-on Couch is designed to be used with the Outlook MRI system and in an X-Ray environment. The indications for use are the same as for standard MR imaging.

**3. Device Description**

The Movable Add-on couch augments the patient handling capabilities of the Outlook MRI system. It interfaces directly with the Outlook patient couch.

The Movable Add-on Couch enables transfer of the patient together with the upper couch plate to and from a movable base directly into the Outlook patient handling system. This makes it possible to do MR imaging without having to lift patient from the supporting surface. The patient can be transported to other imaging modalities using the movable base.

The movable couch also has a radio-translucent upper part making it possible to do fluoroscopic examinations, e.g. with an X-Ray C-arm system, of the patient while on the couch.

The upper couch plate is made of sandwiched bakelite/PVC-foam material. The movable base has two parts; the X-Ray transparent part made of bakelite and the load-carrying parts and coMwrs made of aluminum.

**4. Safety and Effectiveness**

**SUBSTANTIAL EQUIVALENCE CHART**

<b>PARAMETER</b>	<b>MOVABLE ADD-ON COUCH FOR OUTLOOK</b>	<b>PREDICATE</b>
Length	2400 mm	2400 mm
Width of couch plate	625 mm (+ handle 55mm)	625 mm
Height to the edge of the couch	880 mm (upper position)	880 mm (Outlook standard couch K945827)
Portable	yes	no (Outlook standard couch K945827)

<b>PARAMETER</b>	<b>MOVABLE ADD-ON COUCH FOR OUTLOOK</b>	<b>PREDICATE</b>
Maximum patient weight	200 kg	200 kg (Outlook standard couch K945827)
Movement, horizontal	manual	manual (Outlook standard couch K945827)
Movement, vertical	motorized, battery powered	no (Outlook standard couch K945827)
X-Ray Absorption	equal to or below 1.5 mm aluminum	rejection limit 1.2 mm (NRF X-Ray Table K944973)
Intended for Use	MR and X-Ray examinations; movable	MR examinations; stationary (Outlook standard couch K945827)