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VII. Summary of Safety and Effectiveness Information for 510(k) Submission Mobile Operating Table 1132.01

General Information

Proprietary Name:	1132.01
Common Name:	Mobile Operating Table
Classification Name:	Operating room table, AC - powered
Classification:	Class I
Classification Number:	FQO
Intended use:	The device is for use during diagnostic examinations or surgical procedures to support and position a patient.
Legally marketed device	
Proprietary Name:	Betastar 1131.02
Common Name:	Mobile Operating Table
Classification Name:	-
Classification:	Class I
Classification Number:	-
Date of submission:	October 31, 1996
Establishment Name and Adress:	Stierlen-MAQUET AG Kehlerstr. 31 76437 Rastatt / GERMANY
	Contact Person: Reinhard Pfeuffer, OE Telephone: -49/7222/932-219 FAX: -49/7222/932-634
Establishment Registration Number:	8010652

Safety and Effectiveness Information supporting the Substantial Equivalence Determination

Performance Standards

The device complies with	IEC 601-1 respectively EN 60601-1 (UL 2601) Medical Electrical Equipment Part I, General Requirements for Safety IEC 601-1-2, prEN 50115 Medical Electrical Equipment Part II, Particular Requirements for the Safety of Operating Tables
The design, manufacturing and quality control of the device comply with:	DIN EN ISO 29001 DIN EN ISO 46001

Technological Characteristics and the intended use of the device

The operating table has been designed to fulfil the special requirements for patient positioning during surgical treatment. The side rails are provided for fitting additional parts. Before positioning the patient the device has to be covered with sheets. It is an electrohydraulical operated system which can be controlled by means of a hand control box, IR-transmitter, foot switch or with the override. Power is supplied by batteries, which can be recharged by a built-in battery charger. The operating table has the following functions:

Trendelenburg / reverse Trendelenburg positioning	electrohydraulically
Lateral tilt movement (right / left)	electrohydraulically
Leg plate movement (up/down)	electrohydraulically
Back plate movement (up / down)	electrohydraulically
Head plate movement (up / down)	manual
Hight adjustment	electrohydraulically

The table top is subdivided as follows:
Head plate, removable back plate section, back plate, seat plate, leg plates

Each foam upholstered patient supporting section is radiotranslucent and electrically conductive. The radiotranslucention correspond to 21 CFR 1020.30 with an Aluminium Equivalent less than 2 mm.

The development of the design considers the latest issuses of applicable regulations. The following table shows in detail which regulations were applied.

Applied Standards	1132.01	1131.02
IEC 601-1 respectively EN 60601-1 (UL 2601)	yes	yes
IEC 601-1-2	yes	yes
prEN 50115	yes	no
Design, manufacturing and quality control of the device comply with:DIN EN ISO 29001, DIN EN ISO 46001	yes	no