

K961854

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GAYMAR INDUSTRIES, INC.

**Premarket Notification [510(K)] Summary**

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**Date Summary Prepared:** June 17, 1996  
**Device Name:** SPR+ II System  
**Common Name:** Low Air Loss System  
**Classification Name:** Alternating Pressure Air Flotation Mattress per 21 CFR, Section 880.5550  
**Predicate Device:** CLA 1500 System

**Intended use of Device:**

The SPR+II overlay system is a pressure relieving support system intended to reduce the potential for development of pressure ulcers on at risk patients or to be used in the treatment of existing pressure ulcers.

**Description:** The SPR+II System consists of an electromechanical inflation pump control unit which is connected to an overlay through a hose assembly connected to the inflation pump.

**Substantial Equivalence:**

**The following tables, SPR+II substantial equivalence matrix and the safety testing comparison table, summarize the technological characteristics and the nonclinical performance data upon which the substantial equivalence submission was made to the Food and Drug Administration.**

**SPR + II SUBSTANTIAL EQUIVALENCE MATRIX**

5/7/96

<b>CLA-1500</b>	<b>SPR + II</b>
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<b>PERFORMANCE</b>		
Overlay	Single cell with micro-vents for low air loss	Single cell with micro-vents for low air loss
Air Source	Blower	Electro-mechanical reciprocating pump
Pressure control mechanism	Microprocessor controlled pressure relief valve	Microprocessor controlled pressure relief valve
Voltage	120v 60Hz Nominal	120v 60Hz Nominal
Ambient	60-90°F	60-90°F
Tissue interface pressure measurements	Pressure relief	Pressure relief
<b>Safety</b>		
Maximum allowable pressure controlled by	Mechanical relief valve (Below 60 mmHg)	Mechanical relief valve (Below 56 mmHg)
CPR Deflate mechanism	Quick-disconnect feature of hose from pump	Remove screw cap at mattress
<b>Physical characteristics</b>		
Construction (Patient support surface)	Air filled cell used as an overlay	Air filled cell used as an overlay
<b>Function &amp; Intended uses</b>		
Type of therapy provided	Prevention and treatment of pressure ulcers	Prevention and treatment of pressure ulcers
(Primary) Target population	Acute care and alternate care settings	Acute care and alternate care settings
Life Expectancy (pump)	Reusable	Reusable
Life Expectancy (cell)	Support surface, single patient use, replaceable	Support surface, single patient use, replaceable
<b>Approvals</b>	UL 544	UL 2601-1 pending

# COMPARISON OF MAJOR CHARACTERISTICS

<u>Characteristic</u>	<u>CLA-1500</u>	<u>SPR + II</u>
<b>Alerts</b>		
Audible Alerts	yes	yes
Visual Alerts	yes	yes
Auto Reset	yes	yes
Alert Delay	yes	yes
Hi/Lo Pressure Alerts	yes	yes
Out of Range Alert	yes	yes
Hose Disconnect Alert	yes	yes

## Support Surface

CPR Deflate	yes	yes
Low Air Loss	yes	yes
Pressure Relieving	yes	yes
Disposable Support Surface	yes	yes
Pressure Control	Digital (microprocessor controlled)	Setpoints (microprocessor controlled)
Pressure Range (mm Hg)	8-32	18-30*
Remote Pressure Sensing**	yes	no

## Air Control Pump

Digital Pressure Display	yes	setpoint indicator
120 Volt AC	yes	yes
60 Hz	yes	yes
Amperage	1-5	1
Control Panel Lock-out	yes	no
Microprocessor Control	yes	yes
U.L. Listed	yes	Prepared for Submittal
Air Source	DC Blower	Electro-mechanical reciprocating pump

\* Values of SPR+II range are within predicate device range.

\*\* Improvement in design eliminates the need for remote pressure sensing.