



K960620
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APR 25 1996

**PRESSUREGUARD: LOW AIR LOSS MATTRESS SYSTEM
510K SUMMARY**

1.0 SUBMITTER: Span-America Medical Systems, Inc.
ADDRESS: 70 Commerce Center; Greenville, SC 29615
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CONTACT PERSON: Charles B. Mitchell, President & CEO
Wanda J. Totton, Director of Quality

DATE PREPARED: February 8, 1996

2.0 TRADE NAME: PressureGuard: Low Air Loss Mattress System
COMMON NAME: Powered Low Air Loss Mattress System
CLASSIFICATION NAME: Unknown

3.0 PREDICATE DEVICE: PressureGuard® IV, 510K951112.

4.0 DESCRIPTION: The PressureGuard Low Air Loss Mattress System is a powered air flotation mattress which provides a continuous flow of air to the air cylinders as a portion of the air is vented inside the mattress. The air flow is designed to provide and maintain an inflation level to achieve pressure reduction in the prevention and treatment of pressure ulcers.

5.0 INDICATIONS FOR USE: For the prevention and treatment of pressure ulcers.

6.0 SUBSTANTIAL EQUIVALENCE: The product is similar in function and intended use to the PressureGuard® IV, 510K951112 for the Center Mode.