

**SPAN-AMERICA**  
**MEDICAL SYSTEMS, INC.**

K961159

JUN 14 1996

**SPAN-AMERICA HORIZONTAL LOW AIR LOSS MATTRESS SYSTEM  
510K SUMMARY**

- 1.0. SUBMITTER:** Span-America Medical Systems, Inc.  
**ADDRESS:** 70 Commerce Center; Greenville, SC 29615  
**TELEPHONE:** (864) 288-8877  
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- CONTACT PERSON:** Charles B. Mitchell, President & CEO  
Wanda J. Totton, Director of Quality
- DATE PREPARED:** May 28, 1996
- 2.0. TRADE NAME:** Span-America Horizontal Low Air Loss Mattress System
- COMMON NAME:** Powered Low Air Loss Mattress System  
**CLASSIFICATION NAME:** Unknown
- 3.0. PREDICATE DEVICE:** DYNAGUARD ® LOW AIR LOSS MATTRESS SYSTEM, 510K960620
- 4.0. DESCRIPTION:** The Span-America Horizontal Low Air Loss Mattress System is a powered air flotation mattress which provides a continuous flow of air to the air sacks 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:** The Span-America Horizontal Low Air Loss Mattress System is a powered air flotation mattress with low air loss. The pressure-reducing surface is indicated for the prevention and treatment of pressure ulcers.
- 6.0. SUBSTANTIAL EQUIVALENCE:** The product is similar in function and intended use to the DYNAGUARD LOW AIR LOSS MATTRESS SYSTEM, 510K960620.