



K960188

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PRESSUREGUARD: SELECT CARE

510K SUMMARY

- 1.0. **Submitter:** Span-America Medical Systems, Inc.
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- Telephone:** (864) 288-8877
- Contact Person:** Charles B. Mitchell, President & CEO
Wanda J. Totton, Director of Quality
- Date Prepared:** January 8, 1995

- 2.0. **Trade Name:** PressureGuard: SelectCare Mattress System
- Common Name:** Powered Air Flotation Mattress
- Classification Name:** Unknown

- 3.0. **Predicate Device:** PressureGuard IV, 510K951112

- 4.0. **Description:** The PressureGuard SelectCare is a powered air flotation mattress which provides pressure-reducing support within a range of adjustable firmness to meet individual comfort needs. The system also includes a CPR mode, providing a firm surface for performing CPR.

- 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 and CPR Modes.