SPAN-AMERICA
MEDICAL SYSTEMS, INC.

K972486

PressureGuard Turn Select 510K Summary FEB 20 1998

1.	Submitter's Name:	Span-America Medical Systems, Inc.
	Address:	70 Commerce Center Greenville, SC 29615
	Telephone Number:	(864) 288-8877
	Contact Person:	James D. Ferguson, President & CEO Wanda Totton, Director of Quality
	Date Prepared:	October 9, 1997
2.	Trade Name:	PressureGuard Turn Select, Model L
	Common Name:	Alternating Pressure Mattress
	Classification Name:	Alternating Pressure Air Flotation Mattress, CFR 880.5550, Classification No. 80 FMN.
3.	Predicate Device:	PressureGuard IV, 510K953503
4.	Description:	The PressureGuard IV is an air flotation, alternating pressure support system. It consists of a foam shell manufactured with medical grade, polyurethane foam that meets the California Technical Bulletin 117. The perimeter bolsters are designed to safely prompt the patient toward the center of the surface, facilitating safe transfers and edge-of-bed sittings. The inflation system is cradled and securely positioned within the foam shell. Through computerized technology, the internal air pressures of the inflation system are controlled to achieve four operating modes. The CENTER Mode provides a level supine surface. The FIXED ROLL Mode provides automatic turning, turning the patient to the left followed by a 2 hour dwell time, then returning to center for a 2 hour dwell time, followed by a turn to the right followed by a 2 hour dwell time. The CUSTOM ROLL Mode

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by a 2 hour dwell time. The CUSTOM ROLL Mode provides for selection of roll patterns, roll angles and dwell times to meet individual patient needs. The CPR Mode provides a firm surface to aid in CPR Procedures (with a crash board).

A Service Required Feature is provided to alert the health care provider in the event of system malfunction. CPR Alarm and Lock-Out features are also included.

5. **Indications for Use:** For the prevention and treatment of pressure ulcers. Patient lateral rotation of up to 30 degrees may also be used as a preventive tool against further complications associated with critically ill patients or immobility.

6. **Substantial Equivalence:** The product is similar in function and intended used to the PressureGuard IV, 510K953503. The PressureGuard Turn Select utilizes the same foam material, but with a modified design. It uses the same air cylinder design, but with a new material. A new cover fabric has been selected to improve system performance for heavy incontinent situations. Pressure-management with the new design is verified through interface pressure testing performed.

The computerized technology is the same, but the controls have been incorporated into the foot-end of the support surface. A pendant control is provided for user interface, with same buttons and functions as the PressureGuard IV, Model K.

A wall mount transfer is incorporated to supply 12 VAC to the enclosure to reduce thermal load for the controls. As with PressureGuard IV, Model L, the system is designed to conform to UL 544 and CSA 122.25.

The indications for use for the PressureGuard Turn Select are identical to those for the PressureGuard IV Model K.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1998

Ms. Wanda J. Totton
Director of Quality
Span-America Medical Systems, Inc.
P.O. Box 5231
Greenville, South Carolina 29606

Re: K972486
Trade Name: PressureGuard Turn Select
Regulatory Class: II
Product Code: IKZ
Dated: January 14, 1998
Received: January 15, 1998

Dear Ms. Totton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 510K972486

Device Name: Pressure Guard Foam Select

Indications For Use:

For the prevention and treatment of pressure ulcers. Patient lateral rotation of up to 30° may also be used as a preventive tool against further complications associated with critically ill patients or immobility.

Wanda G Dotton
2-20-98

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (GDE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972486

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)