SPAN-AMERICA
MEDICAL SYSTEMS, INC.

K973169

FEB 20 1998

PressureGuard Site Select 510K Summary

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 21, 1997**
2.	**Trade Name:**	**PressureGuard Site Select, Model A**
	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 Site Select is an air flotation, alternating pressure support system which provides for customized selection of surface firmness for a head, upper torso, lower torso, and heel zones.**
5.	**Indications for Use:**	**For the prevention and treatment of pressure ulcers.**
6.	**Substantial Equivalence:**	**The product is similar in function and intended use to the PressureGuard IV, 510K953503. Both systems consists of an air inflation system within a foam shell. The foam shell includes a foam topper with bolsters that frame the mattress. For the PressureGuard IV, four air cylinders run lengthwise within the mattress and operate as two pairs. For the PressureGuard Site Select, the air cylinders run side-to-side and operate as four zones, defined as head, upper torso, lower torso, and heels.**

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1 of 5

For both systems, air in the air cylinders is adjusted to defined pressure set points for four defined modes of operation. For the PressureGuard IV, a Center Mode (supine surface), CPR Mode (firm surface for performing CPR with a crash board), Fixed Roll (30 degree left and right rolls with two-hour dwell times), and Custom Roll (provides for options for roll pattern, roll angles, and dwell times) are provided.

For the PressureGuard Site Select, Normal Mode, Alternating Off; Normal Mode, Alternating On; Heel Relief Mode, Alternating Off; Heel Relief Mode, Alternating On; Contour, and CPR modes are provided. The Normal Mode, Alternating Off Mode is comparable to the Center Mode for PressureGuard IV. The Heel Relief Mode, Alternating Off is comparable to the Center Mode for PressureGuard IV with lowered internal air pressures for the heel zone. The CPR Mode is comparable to the CPR Mode for PressureGuard IV. In addition, alternating pressure modes are options for both the Normal Mode and Heel Relief Modes. The Contour Mode provides for customized adjustment of firmness settings for each of the four zones to meet individual patient needs.

Both products are indicated for the prevention and treatment of pressure ulcers.

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: K973169
Trade Name: PressureGuard Site Select
Regulatory Class: II
Product Code: ENM
Dated: January 26, 1998
Received: January 27, 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): _____

Device Name: Pressure Guard Site Shield

Indications For Use:

For the prevention and treatment of pressure ulcers.

W. Patton
8-7-97

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973169

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

(Optional Format 1-2-96)