

**SAM** MEDICAL  
PRODUCTS<sup>®</sup>

**510(k) Summary**  
**The Seaberg Company, Inc. (dba SAM Medical Products, Inc.)**  
**SAM Chest Seal Product Family**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:     K102403    

**A. Submitter:**

The Seaberg Company, Inc. (dba SAM Medical Products, Inc.)  
27350 SW 95<sup>th</sup> Avenue, Suite 3038  
Wilsonville, OR 97070

**Phone:** 503-639-5474

**Fax:** 503-639-5425

**Contact:** Jack N. McCutcheon  
QARA Manager

**Date Prepared:** August 9, 2010

**B. Device Names:****Trade Name:**

1. SAM<sup>®</sup> Chest Seal with Valve
2. SAM<sup>®</sup> Chest Seal

**Common/usual Name:** Chest Seal

**Classification Name:** Dressing Wound and Burn Occlusive

**C. Predicate Device:** Asherman Chest Bandage, K942757  
Vaseline Petrolatum Gauze, K973511

**D. Device Description:****SAM Chest Seal with Valve**

The SAM Chest Seal with valve is an adhesive dressing composed of a hydrogel based adhesive with a clear backing and check valve. The chest seal is placed over the open chest wound. The skin adhesive holds it in place over the wound. The one way valve prevents air pressure from increasing in the pleural space.

The logo for SAM Medical Products, featuring the word "SAM" in a large, bold, sans-serif font, followed by "MEDICAL PRODUCTS" in a smaller, all-caps, sans-serif font. A horizontal line is positioned below the text.

**SAM** MEDICAL  
PRODUCTS®

### **SAM Chest Seal**

The SAM Chest Seal is an adhesive dressing composed of a hydrogel based adhesive with a clear backing. The chest seal is placed over the open chest wound. The skin adhesive holds it in place over the wound.

### **E. Intended Use:**

- To be used as an occlusive wound dressing.
- To be used as a temporary bandage to treat penetrating chest wounds that could compromise the pleural space of the chest cavity, such as: gunshot wounds, stab wounds and fragment wounds, and to be used in emergency situations and to be left in place only while the patient is transported to the hospital.

### **F. Comparison with the Predicate Device:**

There are no significant differences between the *SAM® Chest Seal Product Family devices* and the predicate devices that would adversely affect the use of the device. The *SAM® Chest Seal Product Family devices* are substantially equivalent to the predicate devices in design, function, materials, and indications for use/intended use.

### **G. Non-clinical Data**

Performance testing demonstrated that the Chest Seal devices perform as well as, or better than, the predicate device.

### **H. Clinical Data**

Clinical data are not included in this submission.

### **I. Conclusions Drawn from Testing**

Based on the data presented here, the SAM Medical Chest Seal devices are substantially equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

The Seaberg Company, Inc.  
% Mr. Jack N. McCutcheon  
27350 SW 95<sup>th</sup> Avenue, Suite 3038  
Wilsonville, Oregon 97070

MAR - 3 2011

Re: K102403

Trade/Device Name: SAM<sup>®</sup> Chest Seal with Valve  
SAM<sup>®</sup> Chest Seal

Regulation Number: 21 CFR 878.4020

Regulation Name: Occlusive wound dressing

Regulatory Class: Class I

Product Code: NAD

Dated: February 10, 2011

Received: February 14, 2011

Dear Mr. McCutcheon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

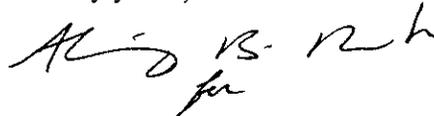
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K102403

Device Name: SAM Chest Seal with Valve  
SAM Chest Seal

### Indications for Use:

- To be used as an occlusive wound dressing.
- To be used as a temporary bandage to treat penetrating chest wounds that could compromise the pleural space of the chest cavity, such as: gunshot wounds, stab wounds and fragment wounds, and to be used in emergency situations and to be left in place only while the patient is transported to the hospital.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K102403