

K962856

18. 510(k) Summary

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Trade Name: Pleur-evac Sahara Adult/Pediatric
Chest Drainage System
Models S-1100, S-1200, S-2100, and S-2200
with Model S-100 Autotransfusion Bag

Common Name: Chest Drainage Systems

Classification Name: System, Drainage, Thoracic, Vacuum
Powered Body Fluid Suction Apparatus

Equivalent Device:

The Pleur-evac Sahara Adult/Pediatric Chest Drainage System Models S-1100, S-1200, S-2100, and S-2200 with Model S-100 Autotransfusion Bag are substantially equivalent in form, fit, function and intended use to the Thora-Klex Model 0077000 Chest Drainage System, cleared for marketing by FDA under 510(k)s #K801043A and #K830671, and the Pleur-evac Model A-6000 Chest Drainage System, cleared for marketing by FDA under 510(k)s #K881252 and #K905768A.

The Model S-100 Autotransfusion Bag, in specific, is substantially equivalent in form, fit, and function, to the currently marketed Pleur-evac Model A-1500 Autotransfusion Bag used with the Pleur-evac Model A-6000 Chest Drainage System, cleared for marketing by FDA under 510(k)s #K 854301, #K881252 and #K884844A.

Device Description:

Pleur-evac Sahara Adult/Pediatric Chest Drainage System Models S-1100, S-1200, S-2100, and S-2200

Deknatel DSP Worldwide, Inc. has recently acquired the Thora-Klex® Chest Drainage System product lines from Davol Inc., C.R. Bard, Inc. Deknatel DSP Worldwide, Inc. has incorporated certain features of the currently marketed Model 0077000 Thora-Klex

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Chest Drainage System with the features of the currently marketed Model A-6000 Pleur-evac[®] Chest Drainage System into a new chest drainage system, the Pleur-evac Sahara Adult/Pediatric Chest Drainage System. Combining the proven technologies from the Thora-Klex and the Pleur-evac into one unit, creates a new, completely dry Pleur-evac Chest Drainage Unit. Features from the Thora-Klex and the Pleur-evac were transferred to the Pleur-evac Sahara unit without design changes.

There are two basic Pleur-evac Sahara Chest Drainage models: the S-1100 Chest Drainage Unit which is shorter, wider and deeper than the standard Pleur-evac unit but more like the Thora-Klex Model 0077000 shape; and the S-2100 Chest Drainage Unit which carries the standard dimensions of the Pleur-evac Model A-6000 Chest Drainage unit. The S-1100 and S-2100 Chest Drainage Units are capable of autotransfusion option, by attaching a Pleur-evac Sahara Model S-100 Autotransfusion Bag. The Models S-1200 and the S-2200 are identical to the Models S-1100 and S-2100, but are provided with a Model S-100 Autotransfusion Bag attached. The Pleur-evac Sahara Chest Drainage are three bottle systems that include a means for integral suction control, a one way seal via a check valve, and a chamber for collecting fluids.

Hangers are located on the right and left sides of the chest drainage unit to provide support for the chest drainage unit when it is suspended from a hospital bed rail.

The Pleur-evac Sahara Models S-2100 and S-2200 are provided with an integral rotating floorstand. These units free stand when placed on a leveled surface with the floorstand in the open position. The floorstand rotates freely from the closed position to the open position. Once open, the floorstand requires the actuation of a lever to return to the closed position. The design of the Pleur-evac Sahara Models S-1100 and S-1200 does not require a rotating floorstand, since the base of the unit acts as a floorstand.

Pleur-evac Sahara Model S-100 Autotransfusion Bag

The Pleur-evac Sahara Autotransfusion Bag, includes an Autotransfusion Bag that contains a rigid top plate assembled onto a flexible vinyl bag. The Autotransfusion Bag is mounted over a wire support frame. The wire frame maintains the bag in an open position during the collection phase of operation. The frame is removed from the bag during the reinfusion phase to allow the bag to collapse and the reinfusion of the collected blood to occur.

The Pleur-evac Sahara Autotransfusion Bag operates with either suction drainage or gravity drainage. During operation with suction drainage, the Autotransfusion Bag is connected to an appropriate Pleur-evac Sahara Chest Drainage unit that is connected to a vacuum source. The patient vacuum is controlled by the Pleur-evac Sahara Chest Drainage System. During operation with gravity drainage, the Autotransfusion Bag is connected to an appropriate Pleur-evac Sahara Chest Drainage unit that is not attached to a suction source.

The Pleur-evac Sahara Autotransfusion Bag is connected to the Pleur-evac Sahara S-1100 Chest Drainage Unit by means of the Easy-Link Adaptor. The adaptor, which is attached to the Autotransfusion Bag, locks into the Easy-Link receptor on the Pleur-evac Sahara Chest Drainage unit. For the Pleur-evac Sahara Model S-2100 Chest Drainage Unit, the Easy-Link Adaptor is removed from the Model S-100 Autotransfusion Bag by the clinician, and the Autotransfusion Bag is attached directly to the side of the Pleur-evac Chest Drainage Unit, using the metal frame on the bag and the hooks provided on the chest drainage unit. This means of attachment is employed by the currently marketed Pleur-evac Model A-6000 Chest Drainage System. Tubing connectors are provided for attaching the Pleur-evac Sahara Autotransfusion Bag to the appropriate Pleur-evac Sahara Chest Drainage Unit. The connectors are color coded for ease of proper connection.

Tubing clamps are located on each of the tubing ports on the Autotransfusion Bag. The tubing clamps must be closed in order to occlude the patient drainage tube prior to disconnecting the connectors. An injection site is located on one set of connectors through which anti-coagulants may be added to the Autotransfusion Bag or from which samples of the drainage fluid may be taken.

A hanger strap located on the top of the unit provides a means for suspending the Autotransfusion Bag from an I.V. pole during reinfusion.

The Models S-100 and the A-1500 Autotransfusion Bags have similar face graphics, box graphics, and instructions for use. The labeling for the Model S-100 Autotransfusion Bag also includes reference and use of the Easy-Link Adaptor.

Intended Use:

The Models S-1100, S-1200, S-2100, and S-2200 covered by this submission are sterile, single use devices, that are intended for postoperative chest drainage.

The Pleur-evac Sahara Model S-100 Autotransfusion Bag is a sterile, non-pyrogenic, single-use device, intended for post-surgical collection and reinfusion of autologous blood from the thoracic cavity when attached to a Pleur-evac Sahara Chest Drainage.

Summary of Technological Characteristic Equivalence:

All features and technology employed in the Pleur-evac Sahara Chest Drainage Systems are derived from either of the predicate devices, the Pleur-evac Model A-6000, or the Thora-Klex Model 0077000 Chest Drainage Systems. Each of these features from the Thora-Klex and the Pleur-evac Chest Drainage Systems were transferred to the Pleur-evac Sahara Chest drainage System unit without design changes.

Summary of Performance Equivalence:

Testing was performed to compare the functional aspects of the proposed Pleur-evac Sahara Chest Drainage System Models S-1100/S-1200, and S-2100/S-2200 to the Pleur-evac Chest Drainage System Model A-6000 and the Thora-Klex Chest Drainage System Model 0077000. The testing also evaluated the effect of the Pleur-evac Sahara Model S-100 Autotransfusion bag connected to the Pleur-evac Sahara Chest Drainage System Models S-1100/S-1200 and the S-2100/S-2200 units when subjected to simulated patient pressure.

Suction control accuracy, airflow capacity, response to patient air leak, system cracking pressure, high negative pressure relief valve performance, negative pressure indicator performance, and Autotransfusion Bag performance were tested and compared.

The Pleur-evac Sahara Chest Drainage Systems met the performance specifications and were found to be comparable to the Pleur-evac Model A-6000 Chest Drainage System and the Thora-Klex Model 0077000 Chest Drainage System.

The components of a Pleur-evac Sahara Chest Drainage System which come into contact with blood to be reinfused, when the system is attached to a Pleur-evac Sahara Model S-100 Autotransfusion Bag, and connected to a patient, are: the inside of the Autotransfusion Bag, the internal components of the Autotransfusion Bag, the Patient Drainage Tube, the connectors with the Injection Site, and the universal connector

The internal components of the Pleur-evac Sahara Model S-100 Autotransfusion Bag are made of the identical materials as the Pleur-evac Model A-1500 Autotransfusion Bag. Therefore, the biocompatibility testing results provided in 510(k) #K854301 apply to the bag and internal components of the Pleur-evac Sahara Model S-100 Autotransfusion Bag.

The Patient Drainage Tube and the Injection Site materials were changed to be free of latex. The biocompatibility testing for the Patient Drainage Tubes and the Injection Site was performed according to the "Biological Evaluation of Medical Devices", ISO 10993 Part-1. Test results indicated that the requirements of ISO 10993 were met, and that the materials are suitable for use in the Patient Drainage Tube and the Injection Site for the Pleur-evac Sahara Model S-100 Autotransfusion Bag.