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510(k) Summary

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Trade Name: Pleur-evac Sahara Plus Model S-1150
Continuous Reinfusion Autotransfusion System

Common Name: Continuous Reinfusion Autotransfusion System

Classification Name: Autotransfusion Apparatus, Class II, Anesthesiology Devices, 21 CFR 868.5830

Equivalent Device:

The Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System is 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, the Pleur-evac Model A-6000 Chest Drainage System, cleared for marketing by FDA under 510(k)s #K881252 and #K905768A, and the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System, cleared for marketing by FDA under 510(k) #K911656A.

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, #K884844A, and used with the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System, cleared for marketing by FDA under 510(k) #K911656A.

Device Description:

Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System

Deknatel DSP Worldwide, Inc., the manufacturer and marketer of Pleur-evac® Chest Drainage Systems, 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 Chest Drainage System with the features of the currently marketed Model A-6000 Pleur-evac Chest Drainage System, and the Model A-9150 Pleur-evac Plus Continuous Reinfusion Autotransfusion System, into a new chest drainage system, the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System.

The dry one-way seal, negative pressure indicator, and the automatic high negative pressure relief valve of the Pleur-evac Sahara Continuous Reinfusion Autotransfusion System, were transferred from the Thora-Klex Chest Drainage unit. The dry suction regulator, air leak meter, positive pressure relief valve, manual high negative pressure relief valve, floorstand, hangers, and the patient drainage tube configuration of the Pleur-evac Sahara Continuous Reinfusion Autotransfusion System were transferred from the Pleur-evac Model A-6000 Chest Drainage unit. The design configuration of the reinfusion port, reinfusion tube, and spike port for continuous reinfusion were transferred from the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System. Each of these features from the Thora-Klex Model 0077000 and the Pleur-evac Models A-6000 and A-9150 were transferred to the Pleur-evac Sahara unit without design changes.

Minor design changes were made to the collection/reinfusion chamber of the Pleur-evac Sahara Plus Model S-1150 when compared to the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System. The collection/reinfusion chamber on the Pleur-evac Sahara Plus Model S-1150 is shorter and deeper than the Pleur-evac Plus Model A-9150 collection/reinfusion chamber. The purpose of this design change was to increase the capacity in the collection/reinfusion chamber.

The Pleur-evac Model A-6000 Chest Drainage Unit and the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System utilize the same components on the patient drainage tube as used on the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System. The patient drainage tube includes a tube, snap lock connectors with injection site, and a universal connector. The material for the patient drainage tube and the injection site on the connectors has been changed to be latex free.

Either a Pleur-evac Sahara Model S-100 Autotransfusion Bag, or a blood transfer bag, may be attached to the Pleur-evac Sahara Model S-1150 to serve as a bag reinfusion system. When autotransfusion is completed, the Model S-1150 may serve as a standard chest drainage collection unit. The Pleur-evac Sahara Model S-100

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 comes with the Easy-Link Adaptor. When attaching the Pleur-evac Sahara Autotransfusion Bag to the Pleur-evac Sahara Plus Model S-1150, 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 Sahara Plus Model S-1150 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 Pleur-evac Sahara Plus Model S-1150 unit. The connectors are color coded for ease of identification for 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.

All of the components, materials, manufacturing processes and specifications are the same for the Pleur-evac Sahara Model S-100 Autotransfusion Bag and the currently marketed Pleur-evac Model A-1500 Autotransfusion Bag, which is used with the Pleur-evac Model A-6000 Chest Drainage System with Autotransfusion Option, or the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System. The differences between the S-100 and the A-1500 Autotransfusion Bags are the Easy-Link Adaptor, and the materials of the Patient Drainage Tube and Injection Site to be latex free. 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 Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System, is a sterile, non-pyrogenic, single use, three chamber collection/reinfusion device that is intended for collection and continuous reinfusion of autologous blood.

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

Summary of Technological Characteristic Equivalence:

All features and technology employed in the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System are derived from either of the predicate devices; the Pleur-evac Model A-6000 Chest Drainage System, the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System, or the Thora-Klex Model 0077000 Chest Drainage System.

The components which make up the one-way seal, negative pressure indicator, and the automatic high negative pressure relief valve of the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System were transferred directly from the Thora-Klex Chest Drainage unit. The components which make up the dry suction regulator, air leak meter, positive pressure relief valve, manual high negative pressure relief valve, and the patient drainage tube of the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System were transferred directly from the Pleur-evac Model A-6000 Chest Drainage unit. The reinfusion port, reinfusion tube, and spike port for continuous reinfusion are from the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System. Each of these features from the Thora-Klex and the Pleur-evac Chest Drainage Systems were transferred to the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System unit without design changes.

The Collection/Reinfusion Chamber in the Pleur-evac Sahara Plus Model S-1150 is larger than the collection/reinfusion chamber in the Pleur-evac Plus Model A-9150. The Pleur-evac Plus Model A-9150 has one compartment, collection/reinfusion chamber with a total capacity of 600 cc. The Pleur-evac Sahara Plus Model S-1150 has a two compartment, collection/reinfusion chamber with a total capacity of approximately 2000cc. Only the blood collected in the first compartment, which is the reinfusion compartment, is able to be reinfused (approximately 1000cc). The second compartment, which is the collection compartment, provides additional collection capacity and is for the overflow of blood from the reinfusion compartment. The Pleur-evac Plus Model S-1150 has the same mesh filter, reinfusion port size, reinfusion tubing, and spike port as the Pleur-evac Plus Model A-9150. The flow pathways for blood collection and for blood reinfusion are substantially equivalent.

Summary of Performance Equivalence:

The Pleur-evac Sahara Chest Drainage Systems have undergone testing to assure their conformance to design specifications, safety and functional requirements. Testing was performed to compare the functional aspects of the proposed Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System to the Pleur-evac Model A-6000 Chest Drainage System and the Thora-Klex Model 0077000 Chest Drainage System. The testing also evaluated the effect of the Pleur-evac Sahara Model S-100 Autotransfusion bag connected to the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion unit 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, autotransfusion bag performance, carrying handle strength, floorstand performance, and hanger to post strength were tested and compared.

The Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System has the same mesh filter, reinfusion port size, reinfusion tubing, and spike port as the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System. Therefore, the blood pathway and blood flow reinfused to the patient remains equivalent, and no additional testing was performed.

The suction control accuracy at each of the set points met specification on each of the units. The Pleur-evac Sahara air flow capacity was comparable to that of the currently marketed Thora-Klex and Pleur-evac Chest Drainage Systems. The Pleur-evac Sahara response to air leak was comparable to that of the currently marketed Pleur-evac Chest Drainage Systems. The Pleur-evac Sahara system and valve cracking pressure performance was functionally comparable to that of the currently marketed Thora-Klex Chest Drainage System. The Pleur-evac Sahara high negative pressure relief valve performance was functionally comparable to that of the currently marketed Thora-Klex Chest Drainage System. The Pleur-evac Sahara negative pressure indicator performance was functionally comparable to that of the currently marketed Thora-Klex Chest Drainage System. Substantial equivalence was demonstrated between a Pleur-evac Model A-6000 Chest Drainage Unit connected to an A-1500 Autotransfusion Bag, and the Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System connected to a S-100 Pleur-evac Sahara Autotransfusion Bag.

The components of a Pleur-evac Sahara Plus Model S-1150 Continuous Reinfusion Autotransfusion System which come into contact with blood during continuous reinfusion are: the universal connector, the patient tube, the snap-lock connectors and the injection site, the collection/reinfusion chamber, the mesh filter, the reinfusion tubing and the spike port. These parts are made of the identical materials as used with the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System, with exception of the materials for the patient tube and the injection site. The biocompatibility testing for the patient drainage tube and the injection site was performed according to the "Biological Evaluation of Medical Devices", ISO 10993 Part-1. Test results indicate that these materials met the requirements of ISO 10993, and that these materials are suitable for use in the patient drainage tube and the injection site. For the other materials which come in contact with blood during continuous reinfusion, the biocompatibility testing results were included in the Pleur-evac Plus Model A-9150 Continuous Reinfusion Autotransfusion System 510(k) #K911656A.

When the Pleur-evac Plus Model S-1150 Continuous Reinfusion Autotransfusion System is attached to a Pleur-evac Sahara Model S-100 Autotransfusion Bag and connected to a patient, the components which come into contact with blood during autotransfusion are: the universal connector, the patient tube, the snap-lock connectors and injection site, the inside of the Autotransfusion Bag, and the internal components of

the Autotransfusion Bag. The Autotransfusion Bag and internal components of the Pleur-evac Sahara Model S-100 Autotransfusion Bag, and the connectors, 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.