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**510(k) SUMMARY
DEKNATEL DSP**

Pleur-evac® Autotransfusion Blood Recovery Bag

1. DATE PREPARED

October 8, 1996

2. SPONSOR INFORMATION

Address: Deknatel DSP Worldwide, Inc.
600 Airport Road
Fall River, Massachusetts 02720

Telephone: 508-677-6600

Contact: Dean E. Ciporkin
Director of Regulatory Affairs

3. DEVICE NAME

Proprietary Name: Pleur-evac® Autotransfusion Blood Recovery Bag
Common/Usual Name: Autotransfusion blood bag
Classification Name: Autotransfusion apparatus

4. DEVICE DESCRIPTION AND INTENDED USE

The Pleur-evac® Autotransfusion Blood Recovery Bag is a blood evacuation and collection device for shed mediastinal or pleural drainage, and is intended to be used in conjunction with DSP Pleur-evac® Continuous Reinfusion Autotransfusion Systems. The device is a flexible PVC bag designed to evacuate and collect filtered blood from a thoracic drainage unit for reinfusion to the patient. The bag contains two spring-loaded plates which are latched together prior to device use. During use, the plates are unlatched and the spring acts against the plates to create a vacuum in the bag thereby drawing the blood into the bag from the Pleur-evac® unit.

5. COMPARISON TO PREDICATE DEVICES

The Pleur-evac® Autotransfusion Blood Recovery Bag is identical in design, materials, manufacturing process, function, and intended use to the predicate device (Atrium Self-filling ATS Blood Bag, model 2450 --K883663). The only difference in the two devices is in the actual product labeling, which identifies the specific trade names and information on the specific distributors. Since the Pleur-evac® Autotransfusion Blood Recovery Bag is identical to the predicate device, no additional performance or biocompatibility testing was provided in this submission in order to establish substantial equivalence of the device to the predicate product.