

11 510(k) Summary

11.1 Applicant

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11.2 Device Name

Proprietary Name: None

Common Name: Plasma Bag

Classification Name: Container, Empty, for Collection and Processing of Blood and
Blood Components

Classification Code: 81 KSR

11.3 Predicate Device

The Medsep Plasma Bag is substantially equivalent to the Medsep Plasma Bag,
Ref. 510(k) No. BK 920027.

11.4 Description Of Device

The Plasma Bag consists of the following parts: a container, a bag port, tubing, and a bowl connector or a luer adapter. The device is connected to an automated plasmapheresis machine for the collection of plasma. Following collection, the unit of plasma is frozen and stored until use.

11.5 Intended Use

The intended use of the Medsep Plasma Bag is for the collection and storage of plasma.

11.6 Comparison Of Device To Predicate Device

The Medsep Plasma Bag has the same general design, materials, and intended use as the predicate, Medsep Plasma Bag, Ref. 510(k) No. BK920027. This device differs from the predicate in that the supplier of the EVA resin for the proposed container is different from that of the predicate device. Both materials passed the requirements of the biocompatibility tests performed. The proposed container was compared to the predicate container. Evaluations of protein interaction, leakage under pressure, seam strength, and breakage under simulated shipping conditions, demonstrated no differences between the containers. It was concluded from these studies that these two containers are substantially equivalent.

11.7 Statement Of Substantial Equivalence

The Medsep Plasma Bag is substantially equivalent to the legally-marketed predicate Medsep Plasma Bag in design, function and intended use.