

BK000032 9-27-2000

Appendix 3
Updated Section 10 510(k) Summary

10 510(k) Summary

10.1 Applicant

Medsep Corporation
A Subsidiary of Pall Corp.
1630 Industrial Park Street
Covina, CA 91722-3419

Primary Contact

Edward J. Nelson, RAC
Medsep Corporation
Director, Regulatory and Scientific Affairs
330 Turnbull Canyon Road
City of Industry, CA 91745

Telephone Number: 626-915-8227

Facsimile Number: 626-915-8253

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10.2 Device Name

Proprietary Name: None

Common Name: Modified Plasma Bag

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

Classification Code: 81 KSR

10.3 Predicate Device

The Modified Plasma Bag is substantially equivalent to the Medsep Plasma Bag,
Ref. 510(k) No. BK 970040.

10.4 Description of Device

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

10.5 Intended Use

The intended use of the Modified Plasma Bag is for the collection and storage of source plasma for further manufacture.

10.6 Comparison of Device To Predicate Device

The Modified Plasma Bag has the same intended use, method of operation, materials (except for the added sampling site), sterilization process, packaging and fundamental scientific technology as the predicate, Medsep Plasma Bag, Ref. 510(k) No. BK970040. The only difference between the predicate device and the modified device is the incorporation of the new component, the sampling site, in the Modified Plasma Bag configuration.

10.7 Statement of Substantial Equivalence

The Modified Plasma Bag has the following similarities to those of the predicate Medsep Plasma Bag which previously received 510(k) clearance:

- the same intended use
- the same method of operation
- the same bag material
- the same tubing material
- the same bowl connector or luer adapter material
- the same packaging and sterilization materials and processes

In summary, the Modified Plasma Bag described in this submission is, in our opinion, substantially equivalent to the legally-marketed predicate Medsep Plasma Bag.