

## 12 510(k) Summary

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### Proposed Device Name:

Device Name: Pall® Platelet Pool and Store Set with Pall® eBDS

Proprietary Name: Pall® Acrodose™ PL System

Common Name: Platelet Pool and Store Set with integral Bacteria Detection  
Sample Set

### CLX HP Storage Bag:

Classification Name: Empty container for the collection and processing of  
blood and blood components (21 CFR 864.9100)

Classification: II

Product Code: KSR

**Pall® eBDS:**

Common Name: Bacteria Detection System Sample Set  
Classification Name: System, detection, bacterial, for platelet transfusion products  
Classification Code: MZC  
Immunology (medical specialty)

**Predicate Devices:**

Predicate Device Name: CLX® Transfer Bags  
Sponsor: Cutter Biological (now Medsep Corp.)  
510(k) Number: BK840010

Predicate Device Name: CLX® Extended Storage Platelet Bag  
Sponsor: Haemonetics Corp.  
510(k) Number: BK860013

Predicate Device Name: Amicus Separator, (with PL2410 extended storage platelet storage bag)  
Sponsor: Baxter Healthcare Corp.  
510(k) Number: BK960005

Predicate Device Name: Citroflex Plasticized PVC Extended Platelet Storage Bag  
Sponsor: Haemonetics Corp.  
510(k) Number: BK980040

Predicate Device Name: Platelet collection sets for the COBE Spectra Apheresis System and the Trima Automated Blood Component Collection System  
Sponsor: Gambro Corp.  
510(k) Number: BK010037

Predicate Device Name: Leukotrap® Platelet Pooling System  
Sponsor: Miles Laboratories Inc. (now Medsep Corp.)  
510(k) Number: BK860001

Predicate Device Name: Pall® eBDS  
Sponsor: Medsep Corporation  
510(k) Number: BK030082

### **Description of the Proposed Device:**

The Pall® Acrodose™ PL System, Platelet Pool and Store Set with eBDS is a sterile, single-use set consisting of a multi-lead tubing manifold for sterile connection to whole-blood-derived platelet concentrates, a 1.5 L CLX® HP extended storage platelet container, and an integral Pall® eBDS Sample Set for use with the Pall® eBDS Oxygen Analyzer (product code: BDS02) for detection of bacteria. The system should be used with ABO identical whole-blood-derived platelets collected in CP2D anticoagulant and leukoreduced using the Leukotrap® RC-PL or Leukotrap® PL Filtration Systems. The shortest expiration date among the units in the pool will determine the final expiration of the pooled product, which is 5 days from the earliest date of blood collection. Each CLX® HP extended storage bag can store  $2.2 - 5.8 \times 10^{11}$  platelets, from 4 to 6 platelet concentrates, at a platelet concentration of  $\leq 2.0 \times 10^6/\mu\text{l}$ , in a volume of 180 – 420 ml.

### **Intended Use of the Proposed Device:**

The Pall® Acrodose™ PL System, Platelet Pool and Store Set with eBDS, is intended to be used to pool and store whole-blood-derived, leukocyte-reduced platelets in the CLX® HP extended storage bag for up to 5 days and, with the Pall® eBDS Oxygen Analyzer, in qualitative procedures to detect aerobic and facultative anaerobic microorganisms (bacteria) in the pooled platelets for quality control purposes.

### **Comparison to Predicate Devices:**

The predicate devices include the use of sterile, single-use plastic containers and tubing sets, including the use of CLX® PVC for some of the extended storage containers. The intended uses of these devices include both the collection or pooling and the extended storage of a therapeutic dose of platelets to be used for transfusion. The integral Pall® eBDS Sample Set is equivalent to the predicate Pall® eBDS. Based on the similarity of intended use, materials, basic scientific technology, and the clinical and non-clinical studies substantial equivalence is claimed.

**Non-Clinical Tests Submitted:**

Studies were conducted in four sites to evaluate the *in vitro* quality of pre-storage pooled platelet concentrates stored five days. Two sites compared the results to standard 5-day platelet concentrates stored individually in the CLX® satellite/transfer bags and pooled post-storage. These studies demonstrated no differences of clinical significance in platelet quality between the two products. Two other sites conducted studies to evaluate the Pool and Store bag's ability to handle a wide range of platelet concentrate volumes and yields. Results showed satisfactory pH maintenance and platelet storage quality with platelet yields ranging from 1.60 - 6.26 x 10<sup>11</sup>/unit. There was no evidence of coagulation activation or excess complement generation in the pre-storage pooled products. There was no indication of any mixed lymphocyte reaction with storage up to five days.

Bacteria detection studies using the integral Pall® eBDS were conducted on a total of 156 pools of whole-blood-derived, leukocyte-reduced platelet concentrates. Ten of the pools auto-sterilized and were not detected. In an initial study, individual PCs were inoculated with low levels (target dose of 1-15 CFU/ml) of various bacteria. After 24 hours, either the PC was mixed with 5 other PC to form a pool, or 10 ml of the PC were removed and mixed with 10 ml from 5 other non-inoculated PC to form a "pool". Samples of the pools were taken for culture (CFU/ml) and eBDS testing immediately after pooling. Samples were incubated at 35°C for 24 hours, followed by testing for bacteria by measuring % oxygen. A second study was conducted to obtain additional data of the faster growing bacteria at lower CFU/ml levels. In this study, after inoculation (target dose of 1-25 CFU/ml) 10 ml aliquots of the inoculated PC and 5 other non-inoculated PC were pooled only 0.5 to 2 hours after inoculation. As in the first study, samples of these pools were taken for culture (CFU/ml) and eBDS testing immediately after pooling. Samples were incubated at 35°C for 24 hours, followed by testing for bacteria by measuring % oxygen.

The Pall® eBDS permitted detection of aerobic and facultative anaerobic bacteria from leukoreduced platelet pools having bacteria levels of ≤ 5 CFU/ml. Of the 146 inoculated pools tested, 145 were detected. The one that was missed had a value of 1 CFU/ml and no bacteria were cultured from the sample contained within the eBDS sample pouch. In summary, these studies have shown 99.3% detection was achieved with testing leukocyte-reduced platelet pools contaminated with ≤ 5 to > 51 CFU/ml of bacteria.

**Clinical Tests Submitted:**

One center conducted a double blind, randomized block, non-inferiority design study comparing results of transfusions of pre-storage pooled platelet concentrates stored in the CLX® HP Pool and Store bag and standard platelet concentrates stored individually in CLX® satellite/transfer bags and pooled post storage. Statistical analysis revealed no significant difference in corrected count increments between the two product types.

**Conclusion:**

Based on the studies presented, pre-storage pooling of whole-blood-derived leukoreduced platelet concentrates is not associated with any reduction in the quality of stored platelets. There is no evidence of a mixed lymphocyte reaction, coagulation or complement activation by pre-storage pooling and storage to day five. Substantial equivalence to the predicates is claimed based on similarity of intended use, materials, basic scientific technology, and performance.