

Section 5 – 510(k) Summary

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Device Name: Proprietary Name: Pall® Acrodose™ PL System
Common Name: Platelet Pool & Store Set
Classification Name: Empty container for the collection and
processing of blood and blood components
(21 CFR 864.9100)
Classification Code: KSR
Panel: Immunology

Predicate Device: Pall® Acrodose™ PL System, Platelet Pool & Store Set with eBDS
(BK050034)

Description of Device:

The Pall® Acrodose™ PL System is a sterile, single-use, pooling and storage set consisting of a multi-lead tubing manifold for sterile connection to whole-blood-derived platelet concentrates and a 1.5 L CLX® HP extended storage platelet container. The set 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 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:

The Pall® Acrodose PL System 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 when coupled with a device cleared by FDA for detection of bacterial contamination in pooled leukoreduced whole-blood-derived platelets.

Indications for Use Statement:

The Pall® Acrodose™ PL System is indicated for pooling of ABO identical, leukocyte-reduced, whole-blood-derived platelet concentrates and subsequent storage for up to 5 days after blood collection when coupled with a device cleared by FDA for detection of bacterial contamination in pooled leukoreduced whole blood-derived platelets. The Pall® Acrodose™ PL System should be used with whole-blood-derived platelet concentrates collected in CP2D anticoagulant and leukoreduced using the Leukotrap® RC PL or Leukotrap® PL Filtration Systems. 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.

Comparison to Predicate Device:

The proposed device, Pall® Acrodose™ PL System, is similar to the predicate device (BK050034) with the exception of the removal of the Pall® eBDS from the proposed device, and three ports rather than four on the storage bag. All the components, excluding the Pall® eBDS, and materials in the proposed device remain the same as in the predicate device (BK050034).

Performance Testing:

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 $1.6-5.8 \times 10^{11}$ /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.

Clinical Testing:

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 Pool and Store CLX® 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 upon the similarity of design, the identical materials and components of the set, and performance, the Pall® Acrodose™ PL System is substantially equivalent to the predicate device.