

Section 7 – 510(k) Summary

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Proposed Device Name:

Proprietary Name: Acrodose™ PL System

Common Name: Platelet Pool and Store Set

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

Classification: II

Product Code: 81 KSR

Predicate Device: Acrodose™ PL System (BK090007)

Description of Device:

The Acrodose™ PL System is a sterile, single-use set consisting of a multiport six-to-one connector for sterile connection to whole-blood-derived platelet concentrates and a CLX® HP extended storage platelet container. 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 $\leq 2.3 \times 10^6/\mu\text{L}$, in a volume of 180 – 420 mL.

Intended Use:

The 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 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 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 $\leq 2.3 \times 10^6/\mu\text{L}$, in a volume of 180 – 420 mL.

Comparison to Predicate Device(s):

With the exception of the multiport six-to-one connector that is made of ABS, the FDA has previously approved/cleared all of the materials and components used in the proposed device. Identical to the predicate device, the proposed product is a sterile, single-use set that is designed for sterile connection to platelet concentrate units. The intended use of both devices is the same and includes pooling and extended storage of a therapeutic dose of platelets to be used for transfusion.

Conclusion:

Based on the similarity of intended use, basic scientific technology, dimensions, fit, and design, substantial equivalence is claimed.