5 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided.

510(k) Summary

I. SUBMITTER

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II. DEVICE

Trade Name of Device:	IMUGARD WB PLT Platelet Pooling Set
Common or Usual Name:	Platelet Pool and Store Set with Filter
Classification Name:	Container, empty, for collection & processing of blood & blood components
Regulatory Class:	In accordance with 21 CFR 864.9245(b), the classification for this device is Class II.
Product Code:	KSR

III. PREDICATE DEVICE

Table 5.1: Predicate and Reference Device Information

Device	Product Classification	Trade Name Of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	KSR	IMUGARD WB PLT Platelet Pooling Set	Terumo BCT	BK210658

IV. DEVICE DESCRIPTION

This 510(k) is to extend the intended use of the IMUGARD WB PLT Platelet Pooling Set to include platelets derived using the Reveos® Automated Whole Blood Processing System. There are no changes to the design or use of the device.

A. Device Identification

The IMUGARD WB PLT Platelet Pooling Set, hereafter referred to as IMUGARD, can be used to leukoreduce (LR), pool and store up to six single units of whole blood derived platelets. For platelets prepared through manual methods, LR and pooling occur on Day 1. For platelets prepared by Reveos Automated Whole Blood Processing System, LR and pooling occur on Day 1 or Day 2. The resulting platelet product is comparable to a single apheresis therapeutic dose and can be stored up to seven days.

B. Device Characteristics
IMUGARD is an ethylene oxide (ETO) sterilized, single use disposable set.

C. Device Description
IMUGARD is designed to allow the attachment of up to six (6) Whole Blood Derived Platelet (WBDP) concentrates for filtration, pooling and storage. WBDPs can be prepared using commercially available manual/semi-automated blood collection systems or automated blood processing systems. Up to 6 single units of WBDPs are sterile docked to the pooling arms and are then gravity drained through a leukoreduction filter. The leukoreduced and pooled platelet product then enters the ELP platelet storage bag (ELP bag). A sampling assembly is attached to the ELP bag. The sampling assembly allows aseptic removal of a sample from the ELP bag for subsequent bacterial or other applicable testing conducted by the blood center. The platelet pooling set allows for the combination of WBDPs to create a leukoreduced product that is comparable to a single apheresis therapeutic dose.

D. Environment of Use
IMUGARD is intended to be used in blood centers, hospitals and healthcare facilities.

E. Materials of Use
IMUGARD is generally comprised of Polyvinyl chloride (PVC) components with variable plasticizers depending on the component. The ELP bag is constructed of Polyvinyl chloride (PVC) citrated.

F. Key Performance Specifications/Characteristics of the Device
IMUGARD is designed to allow the attachment of up to six (6) Whole Blood Derived Platelet (WBDP) concentrates for filtration, pooling and storage in the ELP bag. Single units of WBDPs are sterile docked to the pooling arms and are then gravity drained through a leukoreduction filter. A sampling assembly allows aseptic removal of a sample from the ELP bag for subsequent bacterial or other applicable testing conducted by the blood center. The platelet pooling set allows for the combination of WBDPs to create a leukoreduced product that is comparable to a single apheresis therapeutic dose.

V. INTENDED USE
IMUGARD WB PLT Platelet Pooling Set is intended to be used to leukocyte-reduce, pool and store whole-blood-derived platelets. For platelets prepared through manual methods, leukoreduction and pooling occur on Day 1, the day after whole blood collection and processing, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. For platelets prepared by the Reveos® Automated Blood Processing System, leukoreduction and pooling occur on Day 1 or Day 2, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. Additionally, for platelet units stored past 5 days and through 7 days, every pooled platelet product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."

VI. LABELING COMPARISON
A comparison of IMUGARD labeling with the predicate device to establish substantial equivalence is provided in **Table 5.2**.

Table 5.2: Labeling Comparison

Category	Predicate Device (BK210658)	Subject Device	Comparison
Intended Use	IMUGARD WB PLT Platelet Pooling Set is intended to be used to leukocyte-reduce, pool and store whole-blood-derived platelets. Leukoreduction and pooling occur on Day 1, the day after whole blood collection and processing, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. Additionally, for platelet units stored past 5 days and through 7 days, every pooled platelet product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."	IMUGARD WB PLT Platelet Pooling Set is intended to be used to leukocyte-reduce, pool and store whole-blood-derived platelets. For platelets prepared through manual methods, leukoreduction and pooling occur on Day 1, the day after whole blood collection and processing, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. For platelets prepared by the Reveos® Automated Blood Processing System, leukoreduction and pooling occur on Day 1 or Day 2, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. Additionally, for platelet units stored past 5 days and through 7 days, every pooled platelet product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."	The intended use is identical for whole blood platelets prepared through manual methods. The subject device includes additional text for whole blood platelets prepared by Reveos. There have been no modifications or changes in the safety or effectiveness of the device since clearance; therefore, the difference in platelet preparation does not impact the safety or effectiveness of IMUGARD.

As shown in **Table 5.2**, the intended use is identical for whole blood platelets prepared through manual methods. There have been no modifications of the device since clearance; therefore, the additional text included for whole blood platelets prepared by Reveos does not impact the safety or effectiveness of IMUGARD.

VII. PERFORMANCE DATA

In vitro bench testing performance data was provided in support of the substantial equivalence determination.

Platelets prepared using the Reveos Automated Whole Blood Processing System were pooled and stored using the IMUGARD WB PLT Platelet Pooling Set. Platelets met expectations for leukoreduction, platelet recovery, and pH at the end of storage, whether pooling occurred on Day 1 or Day 2 after collection.

Reveos platelet pools are capable of being stored for up to 7 days in the Terumo BCT ELP storage bag, whether pooling occurs on Day 1 or Day 2 after collection, when used with FDA-cleared or approved bacterial detection tests. Acceptable platelet quality was well-maintained for the 7-day storage duration.

VIII. CONCLUSIONS

Based upon the results of the non-clinical tests performed, IMUGARD is shown to be as safe and effective as the identified predicate device. The information provided in the 510(k) demonstrates that IMUGARD is substantially equivalent to its identified predicate device.