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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Date Prepared: December 8, 2021

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 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	Acrodose™ PLus	**Manufacturer:** Haemonetics Manufacturing, Inc. **510(k) Holder:** Medsep Corporation, A Subsidiary of Pall Corporation	BK080003
Reference	GKT	Trima Acccel® Automated Blood Component Collection System	Terumo BCT, Inc.	BK010037

IV. DEVICE DESCRIPTION

A. Device Identification

The IMUGARD WB PLT Platelet Pooling Set (Catalog Number 41950) consists of six (6) pooling tubes (arms), an integrated platelet leukoreduction filter, a pooled platelet storage bag (ELP bag) and a sampling assembly.

B. Device Characteristics

The IMUGARD WB PLT Platelet Pooling Set (41950) is an ethylene oxide (ETO) sterilized, single use disposable set.

C. Device Description

The IMUGARD WB PLT Platelet Pooling Set 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

The IMUGARD WB PLT Platelet Pooling Set is intended to be used in blood centers, hospitals and healthcare facilities.

E. Materials of Use

The IMUGARD WB PLT Platelet Pooling Set 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

The IMUGARD WB PLT Platelet Pooling Set 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. Leukoreduction and pooling occur on Day 1, which is 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”.

VI. INDICATIONS FOR USE

The IMUGARD WB PLT Platelet Pooling Set, incorporating the ELP bag, is indicated for 5.1×10^{11} platelets, from 4 to 6 platelet concentrates, at a platelet concentration of $0.5 – 2.1 \times 10^{6}/\mu L$, in a volume of 100–400mL. Store up to 7 days from collection at 20-24ºC.

VII. TECHNOLOGICAL COMPARISON

Platelet Pooling is the technological principle for both the subject and predicate devices. It is based gravity drain, leukoreduction and storage. At a high level, the subject and predicate devices are based on the following same technological elements with some differences as shown in the table:

Description	Predicate Device (BK080003)	Subject Device
Intended Use	The Acrodose™ PLus System, platelet Pool and Store Set with In-Line Leukocyte Reduction Filter is intended to be used to pool, leukocyte-reduce, and store whole blood-derived platelets in the CLX® HP extended storage bag for up to 5 days after collection when used with a device cleared by FDA for detection of bacterial contamination in pooled whole-blood-derived platelets.	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.
Material of the Platelet Bag	*CLX® HP Bag:* Polyvinyl chloride (PVC) with tri (2-ethylhexyl) trimellitate (TEHTM) plasticizer	*ELP Bag:* Polyvinyl chloride (PVC) citrated
Platelet Bag Volume	600 mL	Same
Indications for Platelet Bag:	2.2 - 5.8 x 10^{11} platelets, from 4 to 6 platelet concentrates, at a platelet concentration of < 2.0 x 10^{6} µL, in a volume of 180 - 420 mL. Store up to 5 days from collection at 20-24ºC.	5.1×10^{11} platelets, from 4 to 6 platelet concentrates, at a platelet concentration of $0.5 – 2.1 \times 10^{6}/\mu L$, in a volume of 100–400mL. Store up to 7 days from collection at 20-24ºC.
Number of Docking Lines	6	Same
Leukoreduction Filter	Acrodose PL Leukoreduction Filter	Imuflex Leukoreduction Filter
Principal of Operation	Gravity drain	Same
Shelf Life	2 years	Same
Sterilization Method	Ethylene Oxide (ETO)	Same

VIII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

A. Bench Testing – In vitro performance

Terumo BCT conducted *in vitro* study to verify the performance and equivalency of the IMUGARD WB PLT Platelet Pooling Set (Test device) and the Predicate device (Acrodose PLus). A paired design study was used for the *in vitro* study using at least 65 pooled platelet products for primary endpoints. Testing on the platelet pools was performed as follows on days 0, 5 and 7:

Primary Endpoint	Acceptance Criteria
WBC Content	(b) (4)
Platelet Recovery	
$pH_{22^{\circ}C}$ Day 5	
$pH_{22^{\circ}C}$ Day 7	

Secondary endpoints are an indication of platelet function and performance but do not have specific standards, as such differences between Test and Control were calculated for each pair and reported as a mean percentage:

- Swirl
- Lactate
- MPV
- % Lysis
- pCO_2
- Glucose
- ESC
- PS Exposure
- pO_2
- p-Selectin
- HSR
- Morphology Score
- HCO_3
- [PLT]
- LDH

The filtration, leukoreduction, and storage performance of pooled platelets prepared from whole-blood-derived platelets using the Terumo BCT IMUGARD WB PLT Pooling Set and stored in the ELP platelet storage bag met the acceptance criteria for all primary endpoints: filter recovery, WBC content, and pH_{22} C at the end of storage. The IMUGARD Pooling Set performs at least as well as the Acrodose PLus System in terms of platelet recovery, leukoreduction performance and platelet storage. Both sets effectively pool, leukoreduce and store platelets derived from whole blood.

Day 7 comparisons made against historical Trima apheresis platelet products showed differences that were less than 20% for pO_2, glucose concentration, platelet concentration, mean platelet volume, hypotonic shock response, supernatant LDH, and platelet morphology score.

Pooled platelet products prepared and stored using the IMUGARD WB PLT Platelet Pooling Set are capable of being stored for up to 7 days, as demonstrated by acceptable pH and other measures of platelet quality and performance across a battery of platelet function tests. High platelet quality was well-maintained for the 7-day storage duration.

B. Bench Testing – Functional Testing

Verification bench testing has demonstrated that the IMUGARD WB PLT Platelet Pooling Set works as intended and is substantially equivalent to the predicate device. Bench verification testing for the IMUGARD WB PLT Platelet Pooling Set consisted of specification verification, functional and blood performance testing, and human factors of the conditioned and aged disposables

The packaging evaluation for the IMUGARD WB PLT Platelet Pooling Set was conducted in accordance with EN ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices to verify requirements related to the functionality of the set following distribution simulation and aging.

C. Biocompatibility Testing

The biocompatibility evaluation for the IMUGARD WB PLT Platelet Pooling Set was conducted in accordance with ISO 10993-1:2018 and FDA General Guidance on the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process" (September 2020).

Considering all gathered data, the risk assessment indicates that the likelihood of a toxic effect from IMUGARD WB PLT Platelet Pooling Set is low and the associated risk is negligible. The IMUGARD WB PLT Platelet Pooling Set meets the requirements of ISO 10993-1:2018, ISO 14971:2019, and the FDA General Guidance on the Use of International Standard ISO 10993-1:2020 and can be considered safe for use in the pooling and filtration of whole blood derived platelets to produce a pooled platelet unit for transfusion.

D. Sterility Testing

Sterility of the IMUGARD WB PLT Platelet Pooling Set meets requirements outlined in ISO (b) (4) and ANSI/AAMI/ISO (b) (4). IMUGARD WB PLT Platelet Pooling Set have a SAL of (b) (4) Product residuals are tested after sterilization and (b) (4) to have (b) (4) The sets meet the residual limits according to predetermined acceptance criteria.

E. Stability/Shelf Life Testing

IMUGARD WB PLT Platelet Pooling Set has an expiry of 2 years based on accelerated aging data. Real time aging is on-going to support the proposed expiration date.

F. Animal Testing

No animal testing was performed.

G. Clinical Testing

No clinical testing was performed.

IX. CONCLUSIONS

Based upon the functional and in vitro tests performed on the subject device, the IMUGARD WB PLT Platelet Pooling Set is shown to be as safe and effective as the legally marketed predicate device. Additionally, the information provided in this 510(k) demonstrates that IMUGARD WB PLT Platelet Pooling Set can store platelets in the ELP bag up to 7 days.