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:	Reveos® Automated Whole Blood Processing System
Common or Usual Name:	Automated Whole Blood Processing System
Classification Name:	Separator, Semi-Automated, Blood Component
Regulatory Class:	In accordance with 21 CFR 864.9245(b), the classification for this device is Class I
Product Code:	MYY

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	MYY	Atreus Whole Blood Processing System	Terumo BCT	BK080010

IV. DEVICE DESCRIPTION

A. Device Identification

The Reveos® Automated Blood Processing System, hereafter referred to as Reveos, consists of the primary device with embedded software that can separate whole blood into its components and the Reveos SELECT Disposable Set intended to collect and store separated components.

B. Device Characteristics

The device includes valves, sensors and centrifuge which draw in the whole blood, create the appropriate separation, and express the blood components to their respective product bags depending on the protocol.

The Reveos device consists of a centrifuge rotor with four fixed buckets and product bag holders; hydraulic bladders for expression of blood components in their respective product bags and valves for opening/closing the tubing to each product bag when appropriate as signaled by sensors and finally sealing the tubing to the product bags.

C. Device Description

Reveos is an integrated and automated manufacturing system that processes blood components from four units of whole blood. The Reveos System uses centrifugal force to separate one to four units of whole blood into constituent components (plasma, platelets, red blood cells (RBCs), and residual leukocytes). After separation, each product bag is automatically sealed by valves.

D. Environment of Use

The operation of Reveos is intended to be used in blood centers or a hospital-based blood bank.

E. Key Performance Specifications/Characteristics of the Device

The Reveos device is a centrifuge that uses optical sensing to detect the interfaces between different blood components while being centrifuged. A variable speed motor controls the centrifuge speed to ensure optimum separation.

V. INTENDED USE

The Reveos device is intended to automatically separate units of whole blood into blood components.

VI. TECHNOLOGICAL COMPARISON

Provided in **Table 5.2** is a high-level comparison of Reveos to the predicate device.

Table 5.2: Device Comparison Table

Category	Subject Device	Predicate Device	Comparison
Indication for use	The Reveos device is intended to automatically separate units of whole blood into blood components.	The Atreus® Whole Blood Processing System is indicated for the automatic separation and leukoreduction of one unit of whole blood into its blood components: • Red Blood Cells; • Plasma and; • Residual leukocytes The RBCs and Plasma may be transfused.	Similar. Subject has a higher throughput and can process up to four units of whole blood. The difference does not impact the safety or effectiveness of the Subject.
Fundamental Scientific Technology	Centrifugal separation	Centrifugal separation	Same
Variable Speed Centrifugal Separation of Blood Components	Variable speed motor uses optical sensing to detect different blood components	Variable speed motor uses optical sensing to detect different blood components	Same

Category	Subject Device	Predicate Device	Comparison
Auto-balancing of centrifuge rotor	Processes up to **four** units of whole blood with an auto-balancing centrifuge. Up to three counter-balance bags can be used.	Processes one unit of whole blood with an auto-balancing centrifuge.	Similar. The same technology is used; however, Subject has a higher throughput and can process up to four units of whole blood.
Blood Component Interface	Electronic closed loop feedback control	Electronic closed loop feedback control	Same
Controlled Expression of Blood Components	Use of a hydraulic pump and valves	Use of a hydraulic pump and valves	Same
Use of valves to direct fluid pathways	Valves facilitate correct routing of the tubing	Valves facilitate correct routing of the tubing	Same
Radio Frequency (RF) Tube Sealing	RF energy automatically seals the individual product bags	RF energy automatically seals the individual product bags	Same
Software	Software manages the operation of automated whole blood processing	Software manages the operation of automated whole blood processing	Same
Hardware	Electro-mechanical device	Electro-mechanical device	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination. Each type of data is further expanded upon in the sections below:

- Software Testing
- Electrical Safety and Electromagnetic Compatibility Testing
- Functional Performance Testing (Bench)
- Bench Testing – In vitro performance
- Clinical Testing

A. Software Testing

Software verification testing was conducted on the Reveos device. The system complies with ANSI AAMI IEC 62304.

B. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the Reveos device. The system complies with the IEC 61010-1, IEC 61010-2-020, and IEC 61010-2-081 standards for electrical safety. For EMC, the Reveos device is compliant with the prescribed performance criteria for IEC 61326-1 test levels and the pass/fail criteria designated in the test plan for IEC 60601-1-2 test levels.

C. Function Performance Testing (Bench)

Verification bench testing has demonstrated that Reveos works as intended and is substantially equivalent to the predicate device. Bench verification testing for Reveos consisted of specification verification, functional and blood performance testing, human factors and design validation. The testing showed that Reveos performed according to its performance requirements, met its user needs and is usable by the intended users.

D. Bench Testing – *In Vitro* Performance

Terumo BCT conducted an *in vitro* study to demonstrate whole blood (WB) collected into the Reveos SELECT disposable set and processed on the Reveos device produced components that met all in vitro acceptance criteria. The following is a summary of the key findings.

Primary Endpoint

All primary endpoints were met, and the results are summarized in **Table 5.3**.

Table 5.3: Primary Endpoint Summary of Results

Blood Component	Standard	Confidence/ Conformity	Evaluable N	Number of Units Meeting Standard	Mean ± SD (Range)	Lower One–sided 95% CI[a] (threshold)	Result
Plasma Products, LR	Residual WBC content <5 × 10^6 per unit†	95%/95%	65	65	(× 10^6 per unit) 0.21 ± 0.23 (0.00 – 1.34)	0.955 (> 0.95)	Pass
Red Blood Cells, LR	Residual WBC content <5 × 10^6 per unit†	95%/95%	65	65	(× 10^6 per unit) 0.22 ± 0.21 (0.03 – 1.13)	0.955 (> 0.95)	Pass
	Post-Filtration ≥85% recovery of original RBC content†	95%/95%	63	63	(%) 94.0 ± 1.8 (90.5 – 99.8)	0.954 (> 0.95)	Pass
	Hemolysis ≤1% at expiration (42 days)††	95%/95%	65	65	(%) 0.20 ± 0.11 (0.07 – 0.89)	0.955 (> 0.95)	Pass
Platelets (IPU)	Yield ≥5.5 × 10^{10} platelets*	95%/75%	65	58	(× 10^{10} platelets) 9.60 ± 3.59 (0.39 –	0.807 (> 0.75)	Pass
	$pH_{22°C}$ ≥6.2 (at the time of pooling)	95%/95%	65	65	7.225 ± 0.222 (6.520 – 7.735)	0.955 (> 0.95)	Pass

[a] From an exact binomial Clopper and Pearson confidence interval computed for a proportion
† Acceptance Criteria suggested in *Pre-Storage Leukocyte Reduction of Whole Blood Components Intended for Transfusion* FDA Guidance for Industry
†† Acceptance Criteria suggested in Vostal, Jaro Presentation: FDA Evaluation of Red Cell Products, Laboratory of Cellular Hematology OBRR, CBER, FDA on October 6, 2016
*Acceptance Criteria suggested in 21 eCFR 640.24 (c): (Platelet) Processing

All Reveos pooled IPU platelet products, prepared and stored using the IMUGARD WB PLT Platelet Pooling Set, 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.

Safety

Two device deficiencies (DDs) were reported. One resulted in removing and discarding the disposable set from evaluation. No DDs resulted in AEs.

E. Clinical Studies

A clinical study was conducted to evaluate whether the leukoreduced red blood cells (LR-RBCs) derived from whole blood (WB) and processed with the Reveos System met acceptance criteria for 24-hour recovery after 42-day storage.

Device Performance Study

The clinical study was a prospective, open-label, multicenter study to evaluate WB derived red blood cells (RBCs) processed using the Reveos System.

Location of Study

The study was conducted under IDE 27752 at locations within the United States only.

Primary Endpoint

The primary efficacy endpoint of this study was RBC 24-hour recovery using single label (Cr-51) and dual label with Cr-51/Tc-99m. For the single label method, there were 23 successes and 3 failures with a mean 24-hour recovery value of 83% (SD = 9%) and a one-sided 95% lower confidence limit for the proportion of successes of 73%. For the dual label method, there were 24 successes and 2 failures with a mean 24-hour recovery value of 90% (SD = 9%) and a one-sided 95% lower confidence limit of 78%.

Both single label (Cr-51) and dual label Cr-51/Tc-99m met the three FDA criteria of 1) LR-RBC mean 24-hour recovery ≥75% with 2) SD ≤ 9% and 3) a one-sided lower confidence limit for the population proportion of RBCs in vivo recovery of 70% with a "success" being LR-RBC recovery >75%.

Safety

Three confirmed DDs were reported. Out of the three DDs, one resulted in the participant discontinuing from the study. Two out of the three confirmed DDs did not result in discontinuation of the participants and were addressed by replacements of affected parts. No DDs resulted in AEs.

Overall, no safety signals were observed in this study. All reported Procedure-Emergent Adverse Events (PEAEs) were anticipated, related to medical history or had been previously reported as potential AEs during a blood donation. There were no device related PEAEs or Unanticipated Adverse Device Effects (UADEs) reported during this study. All PEAEs reported during the study were related to the study procedures; no PEAEs were related to the investigational device. There were no device related PEAEs or UADEs observed during this study.

Summary

Based on the clinical performance, Reveos worked as expected, performed in safe manner, and met FDA's criteria for in vivo 24-hour recovery after 42-day storage.

VIII. CONCLUSIONS

Based on the non-clinical and clinical tests performed on Reveos, it is as safe and effective as the predicate device. The information provided in the 510(k) demonstrates that Reveos is substantially equivalent to its identified predicate device.