510(k) Summary
BK210591

I. SUBMITTER

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II. DEVICE

Trade Name of Device: Platelet-Rich Plasma (PRP) Procedure Pack
Common or Usual Name: Platelet and Plasma Separator for Bone Graft Handling
Classification Name: Platelet and Plasma Separator for Bone Graft Handling
Regulation Number: 21 CFR 864.9245
Regulation Name: Automated blood cell separator
Product Code: ORG

III. PREDICATE DEVICE

Table 1: Predicate Device Information

Device	Classification Product Code	Trade Name of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	ORG	Harvest PRP Separation System	Terumo BCT, Inc.	BK130068

IV. DEVICE DESCRIPTION

A. Device Identification

The Platelet-Rich Plasma (PRP) Procedure Pack is designed specifically for use with a Class I centrifuge device, SmartPrep Centrifuge System, cleared by FDA in K991430. The Platelet-Rich Plasma (PRP) Procedure Pack come in multiple configurations to accommodate user needs. The Platelet-Rich Plasma (PRP) Procedure Pack is comprised of a Process Kit and a Blood Draw Kit manufactured and sterilized by Terumo BCT, Inc. (Terumo BCT), and a Convenience Kit which includes FDA cleared off-the-shelf components to meet the needs of the end user. All Procedure Packs contain a Processing Kit with either a 30mL or 60mL process disposable with the main differences to include the addition of a Blood Draw Kit, an IV Start Pack, alcohol pads, Anti-Coagulant Citrate Dextrose (ACDA) solution, and syringes. **Table 2** described below is a list of catalog numbers and a description of the various Platelet-Rich Plasma (PRP) Procedure Packs.

Table 2: Procedure Pack Catalog Numbers and Procedure Pack Descriptions

Catalog Numbers	Name of the Platelet-Rich Plasma (PRP) Procedure Pack	High-level Description
51400	PC-30 PRP Procedure Pack	PRP Procedure Pack comprised of three sub-components: 1) Process Kit, 2) Blood Draw Kit, and 3) Convenience Kit. Within the Process Kit, a 30mL Process Disposable is included to process 30mL autologous platelet-rich plasma from a small sample of blood. This catalog number is for Healthcare or Clinic Use only.
51401	PC-60 PRP Procedure Pack	PRP Procedure Pack comprised of three sub-components: 1) Process Kit, 2) Blood Draw Kit, and 3) Convenience Kit. Within the Process Kit, a 60mL Process Disposable is included to process 60mL autologous platelet-rich plasma from a small sample of blood. This catalog number is for Healthcare or Clinic Use only.
51404	APC-30 PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process Kit, a 30mL Process Disposable is included to process 30mL autologous platelet-rich plasma from a small sample of blood. This catalog number is for Healthcare or Clinic Use only.
51405	APC-30i PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process Kit, a 30mL Process Disposable is included to process 30mL autologous platelet-rich plasma from a small sample of blood. This catalog number does not include an IV Start Pack in the procedure pack configuration. This catalog number is for Healthcare or Clinic Use only.
51406	APC-60 PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process Kit, a 60mL Process Disposable is included to process 60mL autologous platelet-rich plasma from a small sample of blood. This catalog number is for Healthcare or Clinic Use only.
51407	APC-60i PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process Kit, a 60mL Process Disposable is included to process 60mL autologous platelet-rich plasma from a small sample of blood. This catalog number does not include an IV Start Pack in the procedure pack configuration. This catalog number is for Healthcare or Clinic Use only.
51408	APC-120 PRP Procedure Pack	PRP Procedure Pack comprised of three sub-components: 1) Process Kit, 2) Blood Draw Kit, and 3) Convenience Kit. Within the Process Kit, two (2) 60mL Process Disposables are included to process 120mL autologous platelet-rich plasma from a small sample of blood. This catalog number is for Healthcare or Clinic Use only.
51414	APC-30n PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process kit, a 30mL Process Disposable is included to process 30mL autologous platelet-rich plasma from a small sample of blood. This catalog number does not include Alcohol Pad and ACDA solution in the procedure pack configuration. This catalog number is for Healthcare or Clinic Use only.
51415	APC-60n PRP Procedure Pack	PRP Procedure Pack comprised of two sub-components: 1) Process Kit and 2) Convenience Kit. Within the Process kit, a 60mL Process Disposable is included to process 60mL autologous platelet-rich plasma from a small sample of blood. This catalog number does not include Alcohol Pad and ACDA solution in the procedure pack configuration. This catalog number is for Healthcare or Clinic Use only.

Catalog Numbers	Name of the Platelet-Rich Plasma (PRP) Procedure Pack	High-level Description
51436	APC-120n PRP Procedure Pack	PRP Procedure Pack comprised of three sub-components: 1) Process Kit, 2) Blood Draw Kit, and 3) Convenience Kit. Within the Process Kit, two (2) 60mL Process Disposable are included to process 120mL autologous platelet-rich plasma from a small sample of blood. This catalog number does not include Alcohol Pad and ACDA solution in the procedure pack configuration. This catalog number is for Healthcare or Clinic Use only.

B. Device Characteristics

The Platelet-Rich Plasma (PRP) Procedure Packs are single-use, prescription-use only medical devices sterilized with Ethylene Oxide (EtO) at Terumo BCT sterilization facility (FDA registration number 1724474).

C. Device Description

The Platelet-Rich Plasma (PRP) Procedure Pack is single-use disposable set used to collect and process autologous peripheral whole blood drawn from the patient/donor's arm intravenously. The Platelet-Rich Plasma (PRP) Procedure Pack is used with the SmartPrep Centrifuge System, cleared by FDA in K991430, that allows separation of plasma and platelets. The Platelet-Rich Plasma (PRP) Procedure Pack is comprised of kits manufactured and sterilized by Terumo BCT as well as off-the-shelf components such as needles, syringes, ACDA, and alcohol pads. The Platelet-Rich Plasma (PRP) Procedure Pack vary by volume of the process disposable, the quantity of off-the-shelf components, and either one or two proprietary process disposables manufactured by Terumo BCT. Multiple configurations of the Platelet-Rich Plasma (PRP) Procedure Packs are manufactured to meet the user needs.

D. Environment of Use

Platelet-Rich Plasma (PRP) Procedure Pack is operated with the SmartPrep Centrifuge System. Health care professionals in hospital, healthcare facility, and clinic medical settings collect autologous peripheral whole blood drawn from the patient/donor's arm intravenously. Health care professionals are commonly trained on the principles of the system by Terumo BCT. Health care professionals have a variety of backgrounds and professional training, and the primary users are expected to be nurses, physicians, and supporting staff.

E. Materials of Use

The Platelet-Rich Plasma (PRP) Procedure Pack is available in multiple configurations to accommodate the needs of the user with the main differences to include a Blood Draw Kit, an IV Start Pack, alcohol pads, Anti-Coagulant Citrate Dextrose (ACDA) solution, and the quantity of process disposables. The Platelet-Rich Plasma (PRP) Procedure Pack is comprised of a Process Kit and a Blood Draw Kit manufactured and sterilized by Terumo BCT and a Convenience Kit that is comprised of off-the-shelf components.

F. Key Performance Specifications/Characteristics of the Device

Within the Platelet-Rich Plasma (PRP) Procedure Pack, a process disposable either a 30mL or 60mL is provided in the Process Kit. The process disposable includes a proprietary, self-calibrating floating shelf that is designed and optimized for concentrating platelets. A material change was made to the predicate 60mL process disposable floating shelf that was FDA cleared

in BK130068. Performance and Biocompatibility testing demonstrated that the new material is substantially equivalent to the predicate material.

V. INTENDED USE / INDICATIONS FOR USE

The Platelet-Rich Plasma (PRP) Procedure Pack is indicated for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

VI. TECHNOLOGICAL COMPARISON

A comparison between the predicate device and the subject device is provided in **Table 3**:

Table 3: Platelet-Rich Plasma (PRP) Procedure Pack Compared to Predicate Device

Device Attribute	**Predicate Device (BK130068)** **Harvest PRP Separation System**	**Subject Device** **Platelet-Rich Plasma (PRP) Procedure Pack**
Intended Use/ Indication for Use	The Harvest Technologies PRP Separation System is indicated for the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improved handling characteristics.	The Platelet-Rich Plasma (PRP) Procedure Pack is indicated for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Device Classification	Class II	Same
Regulation	864.9245	Same
Product Code	ORG	Same
Laboratory Verification	*In vitro* performance testing demonstrated acceptable results (pH, Blood cell count, platelet count, platelet recovery, platelet concentration factor, p-selectin resting, p-selectin ADP activated platelets, platelet aggregation, hypotonic shock response)	Same
Material of the Floating Shelf located in the 30mL Process Disposable	Polystyrene	Same
Material of the Floating Shelf located in the 60mL Process Disposable	Polystyrene	Polystyrene and Styrene-butadiene copolymer
Processing Volumes	One process disposable of 30mL or 60mL, or two process disposables of 60mL (total of 120mL) may be processed	Same

Device Attribute	Predicate Device (BK130068) Harvest PRP Separation System	Subject Device Platelet-Rich Plasma (PRP) Procedure Pack
Kit Contents	Disposable processing units with IV Start Pack, alcohol pads, Anti-Coagulant Citrate Dextrose (ACDA) solution, process disposables, and syringes.	Same
Principle of Operation	Separation based on density	Same
Component Separation Method	Centrifugation	Same
Shelf Life	1- year expiry	2-year expiry
Sterilization Method	Ethylene Oxide (EtO)	Same

VII. PERFORMANCE DATA

The following non-clinical performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device.

A. Bench Testing – In vitro Performance Testing

Terumo BCT conducted *in vitro* study for the material change that was made to the 60mL process disposable floating shelf. The i*n vitro* study was initiated to verify the performance and equivalency of the proposed Platelet-Rich Plasma Procedure Pack (Test device) and the Predicate device that was FDA cleared in BK130068. A paired design study was used for the *in vitro* study using thirty (30) de-identified human units of blood for processing into Platelet-Rich Plasma (PRP) product. Testing on the platelet concentrate were performed to evaluate for:

- pH
- Blood cell count (RBC, WBC)
- Platelet count
- Platelet recovery
- Platelet concentration factor
- P-selectin expression on platelets (on resting and ADP activated platelets)
- Hypotonic stress response
- Platelet aggregation (collagen)

Comparative testing, with saline as control, was conducted to determine if the Platelet-Rich Plasma (PRP) produced by the Platelet-Rich Plasma (PRP) Procedure Pack performs as intended by improving bone graft handling. The PRP was mixed with a solution of 1000 IU Thrombin in 10% Calcium Chloride prior to mixing with the bone graft. Testing involved analyzing the compression forces of bone graft mixed with Platelet-Rich Plasma (PRP) produced by the device and comparing bone graft mixed with saline as the control. The results demonstrated that the PRP produced by the device improved bone graft handling characteristics.

B. Biocompatibility Testing

The biocompatibility evaluation of the Platelet-Rich Plasma Procedure Pack was conducted in accordance with the FDA Guidance document, "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process," September 4, 2020. Biocompatibility for the proposed Platelet-Rich

Plasma (PRP) Procedure Pack is substantially equivalent to the predicate device. Biocompatibility Testing and Test Results are summarized in the table below:

Description of Test	Test Results
Hemolysis Study (ASTM Hemolysis Assay - Direct Contact and Extract Method)	Pass
Testing of Subject vs Predicate Device (ASTM Partial Thromboplastin Time with Sponsor Provided Control)	Pass
Bacterial Reverse Mutation Study	Pass
Biological Risk Assessment	Pass
ISO 10993-18: Chemical Characterization Study	Pass
Cytotoxicity Study using he ISO Elution Method	Pass
ISO Acute Systemic Toxicity Study in Mice	Pass
ISO Guinea Pig Maximization Sensitization Test	Pass
ISO Intracutaneous Study in Rabbits	Pass
Platelet and Leukocyte Counts with Sponsor-Supplied Comparison Article (GLP)	Pass
Subject vs Predicate Device Testing: SC5b-9 Complement Activation Assay with Sponsor Provided Control	Pass
USP Rabbit Pyrogen Study, Material Mediated	Pass

C. Sterility Testing

Platelet-Rich Plasma (PRP) Procedure Packs are validated and meet the requirements outlined in ISO 11135:2014 and ANSI/AAMI/ISO 10993-7:2008. The ethylene oxide cycle was validated using the conservative approach resulting in a minimum of a (b) (4)-log reduction with a Sterility Assurance Level (SAL) of ≤1.0 x 10^-6. Product residuals are tested after sterilization and aeration for 2 days to have ≤ 4mg EO and ≤ 9mg ECH. The Platelet-Rich Plasma (PRP) Procedure Pack meets the residual limits according to predetermined acceptance criteria.

D. Stability/Shelf Life Testing

The shelf life of the Process Kit and Blood Draw Kit within the Platelet-Rich Plasma (PRP) Procedure Pack is claimed to be 2 years based on the 2 year Accelerated Study as the 2-year Real Time study is on-going. The off-the-shelf components provided in the Convenience Kit are purchased as manufactured by the legal manufacturer and have their own shelf life data. These components have been cleared for use under their respective regulatory submissions as described in Section 11 of this 510(k) submission. The overall expiration date of the Platelet-Rich Plasma (PRP) Procedure Pack is determined by the earliest expiration date of all the components.

E. Animal Testing

No animal testing was performed.

F. Clinical Testing

No clinical testing was performed.

VIII. CONCLUSIONS

Based on performance, sterility, biocompatibility, and stability/shelf life testing performed on the proposed Platelet-Rich Plasma (PRP) Procedure Pack, it was determined that it performs as intended in comparison to the legally marketed predicate device. The information provided in the 510(k) demonstrates that the Platelet-Rich Plasma (PRP) Procedure Pack is substantially equivalent to the predicate device.