510(k) Summary

I. SUBMITTER

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Date Prepared: February 2, 2022

510(k) Number: BK210632/0

II. DEVICE

Common Name:	Platelet and plasma separator for bone graft handling
Proprietary Name:	Royal MAXX™ PRP Concentration System
Regulation Description	Automated blood cell separator
Review Panel:	Hematology
Product Code:	ORG
Regulation Number:	21 CFR 846.9245
Device Class:	II

III. PREDICATE DEVICES

The legally marketed primary predicate device for the Royal MAXX PRP Concentration System is the BioCUE Platelet Concentration Kit cleared via BK100027 (cleared May 26th, 2010) as this device shares the same intended use as the Royal MAXX PRP Concentration System (i.e., preparation of PRP from a small sample of a mixture of peripheral blood and bone marrow aspirate) and similar technological characteristics.

The subject concentration device is technologically identical to the device cleared via BK180204 (cleared July 12th, 2018) and BK210563 (cleared April 16th, 2021).

IV. DEVICE DESCRIPTION

The Royal MAXX PRP Concentration System is a sterile, single-use kit of consumables including a concentration device, accessories for bone marrow collection/processing, and ACD-A anticoagulant. The device is used with a standard centrifuge to separate platelets and plasma from a 3:1 mixture of peripheral blood and Bone Marrow Aspirate to provide a means to capture platelet rich plasma (PRP) as a final product.

V. INDICATIONS FOR USE

The Royal MAXX PRP Concentration System is designed to be used at the patient's point of care for the safe and rapid preparation of a platelet rich plasma (PRP) from a small sample of a mixture of peripheral blood and bone marrow aspirate that is mixed with autograft and or allograft bone prior to application to a bony defect for improving handling characteristics.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Royal MAXX Autologous PRP Concentration System is substantially equivalent to the primary predicate BioCUE Platelet Concentration Kit cleared via BK100027 in preparing PRP using a mixture of peripheral blood and bone marrow aspirate. The subject device shares the same intended use and has similar technological features as the primary predicate BioCUE Platelet Concentration Kit. The following table provides a review of the similarities and differences in technological characteristics between the subject Royal MAXX PRP Concentration System with the predicate BioCUE device.

Table 5-1. Substantial Equivalence Matrix for the subject Royal MAXX PRP Concentration System compared to the primary predicate BioCUE Platelet Concentration System (BK100027)

Point of Comparison	Primary Predicate Device BioCUE Platelet Concentration System (BK100027)	Subject Device Proposed Royal MAXX PRP Concentration System (Subject of this 510(k))
Device Construction and Function		
Indications for use	The BioCUE™ Platelet Concentration System is designed to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet-rich-plasma or PRP) from a small sample of blood and bone marrow mixture. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma (PRP) can be mixed with autograft: and/or allograft: bone prior to application to an orthopedic surgical site.	The Royal MAXX PRP Concentration System is designed to be used at the patient's point of care for the safe and rapid preparation of a platelet rich plasma (PRP) from a small sample of a mixture of peripheral blood and bone marrow aspirate that is mixed with autograft and or allograft bone prior to application to a bony defect for improving handling characteristics.

Table 5-1. Substantial Equivalence Matrix for the subject Royal MAXX PRP Concentration System compared to the primary predicate BioCUE Platelet Concentration System (BK100027)

Point of Comparison	Primary Predicate Device BioCUE Platelet Concentration System (BK100027)	Subject Device Proposed Royal MAXX PRP Concentration System (Subject of this 510(k))
Device Material	Injection molded polymer	Same as the Primary Predicate Device.
Device Structure	Cylinder with internal piston, 2 luer ports (fill and aspiration), air vent with internal separator	Same as the Primary Predicate Device.
Method of fluid separation	Centrifugation	Same as the Primary Predicate Device.
Ratio of Peripheral Blood and Bone Marrow Aspirate	3:1	3:1 (Same as Predicate)
Buffy coat layer isolation method	Aspiration of plasma and buffy coat through a piston, which moves in the container due to a pressure differential.	Aspiration of plasma and buffy coat through a drawtube built into an internal separator. The separator starts at the top of the device and is manually moved down through the plasma and buffy coat layers separating them into the upper chamber and leaving the RBC in the lower chamber.
Centrifuge Device	General purpose centrifuge	Same as the Primary Predicate Device.
Centrifugation Time and Speed.	A single spin at 3200 RPM for 15 minutes.	Two spins: 3500 RPM for 4 minutes followed by 3800 RPM for 5 minutes
Accessories Provided	**Component** / **Qty** 30 mL Vial of ADC-A Anticoagulant / 1 Syringe Luer-Lok 30 mL / 3 Syringe Luer-Lok 60 mL / 1 18 Gauge Needle / 5 Alcohol Prep Pad / 2 Tourniquet, 1” x 18”, Sterile / 1 Gauze Pad / 2 Adhesive Tape / 1 Apheresis Needle / 1 Blunt Tip for Bone Aspiration Needle / 1 Bone Marrow Aspiration Needle / 1	**Component** / **Qty** 30 mL Vial of ADC-A Anticoagulant / 1 Syringe Luer-Lok 10 ml / 1 Syringe Luer-Lok 60 ml / 3 Blunt Tip, Needle, 18G x 1 1.2” / 2 Alcohol Prep Pad – Medium / 2 Vacuum Lock Syringe / 1 11G Trocar/Jamshidi kit / 1 Fluid Dispensing Connector / 2
Sterile, Non-pyrogenic	Yes	Same as the Primary Predicate Device.
How Sterilized	Ethylene Oxide	Same as the Primary Predicate Device.
Sterility Assurance Level	10^{-6}	Same as the Primary Predicate Device.

Table 5-1. Substantial Equivalence Matrix for the subject Royal MAXX PRP Concentration System compared to the primary predicate BioCUE Platelet Concentration System (BK100027)		
Point of Comparison	**Primary Predicate Device BioCUE Platelet Concentration System (BK100027)**	**Subject Device Proposed Royal MAXX PRP Concentration System (Subject of this 510(k))**
Packaging Design	Tyvek Tray.	Same as the Primary Predicate Device.
How Used	Single use only	Same as the Primary Predicate Device.

As note in the table above, there are many similarities between the Royal MAXX PRP Concentration System and the predicate BioCUE device. The subject device is substantially equivalent to the predicate BioCUE device with respect to structure, material, and general fluid separation method. The following provides additional review and discussion for each item identified in Table 5-1 in regards to the comparison of the subject and predicate BioCUE device.

- **Indications for Use** - The "Indications For Use" for the predicate BioCUE device are stated slightly different; however, the intended use is the same for both devices. The indication for use statement for the Royal MAXX PRP Concentration System has been standardized to meet the requirements of most recently cleared devices under procode ORG.
- **Device Materials** - The device material of the Royal MAXX PRP Concentrator is substantially equivalent to the primary predicate device: The Royal MAXX PRP Concentrator device and the predicate are made from a molded polymer.
- **Device Structure** - The structure of the Royal MAXX PRP Concentrator device and the predicate are substantially equivalent: They both consist of a thin walled, molded, cylinder shaped body of similar size.
- **Method of fluid separation** - The fluid separation method of the Royal MAXX PRP Concentrator is substantially equivalent to the predicate device using a well-known method of separating blood into layers based on cell density.
- **Buffy Coat Layer Isolation Method** - In the Royal MAXX PRP Concentrator and the primary predicate device, preparation of PRP requires isolating the buffy coat layer to separate the plasma and buffy coat from the red blood cells (RBC.) The Royal MAXX PRP Concentrator device uses an internal separator with a drawtube built into it. The separator starts at the top of the device and is manually moved down through the plasma and buffy coat layers, via the lead screw. The separator displaces the fluid forcing it to exit the bottom chamber, through the drawtube, into the upper chamber. The plasma and buffy coat are now isolated from the RBC which is still in the lower chamber.

  The predicate device uses a piston with an aspiration tube attached through it to access the bottom side of the piston. The piston starts at the top of the fluid level and is sealed to the inside of the device body. A suction force is applied through the aspiration tube to the bottom side of the piston using a syringe. The plasma and buffy coat are aspirated into the syringe leaving the RBC in the device.
- **Centrifuge/Centrifugation Time and Speed** - Both the Royal MAXX Concentrator

and predicate are used with a commercially available general-purpose centrifuge. The Royal MAXX Concentrator creates PRP in two centrifugation steps using a single concentration container. The device is spun at 3500 RPM for 4 minutes, then again at 3800 RPM for 5 minutes. In contrast, the predicate system spins only once at 3200 RPM for 15 minutes.

- **Single-Use/Sterile** – The subject and predicate device are single use and sterilized via EO and labeled as non-pyrogenic.

VII. PERFORMANCE DATA

Sterilization Validation

The Royal MAXX PRP Concentration System is sterilized via a validated (b) (4) process to a Sterility Assurance Level (SAL) of (b) (4) per ISO (b) (4) *Sterilization of health-care products —* (b) (4) *— Requirements for the development, validation and routine control of a sterilization process for medical devices.* (b) (4) residuals are within accepted limits. Bacterial endotoxin per (b) (4) was conducted to demonstrate that the device meets pyrogen limit specifications.

Shelf Life/Device Integrity

Packaging validation, shelf-life, and device integrity testing (consistent with that described in BK210563) were performed to assure that the kit configuration did not adversely alter the subject device. Testing was conducted to evaluate the functional and structural integrity of the product and its packaging following worse-case conditioning including 2 times sterilization and post environmental conditioning, simulated shipping, and aging. The results demonstrated that the device and packaging structural and functional integrity remain intact following conditioning and the data support a 1-year shelf-life for the device.

Biocompatibility Testing

As there has been no change in the PRP concentration device and packaging materials, biocompatibility testing as described in BK210563 have been leveraged for this current 510(k) to demonstrate that the concentrator device materials are compatible with human use. Biocompatibility testing included evaluation of cytotoxicity, sensitization, intracutaneous toxicity, acute systemic toxicity, material mediated pyrogenicity and direct and indirect hemolysis.

Bench Testing

Comparative testing was performed that indicates the PRP prepared with the Royal MAXX PRP Concentration System using a small sample of a mixture of peripheral blood and bone marrow is substantially equivalent to the primary predicate device, the BioCUE Platelet Concentration Kit, which is specifically indicated for the rapid preparation of PRP from a mixture of peripheral blood and bone marrow aspirate similar to the device subject of this 510(k). Testing included

evaluation of the following parameters: Cell counts (white blood cell, red blood cell and platelet counts), platelet yields, platelet concentration factor, pH, platelet activation, platelet aggregation and bone graft retention.

VIII. CONCLUSION

The proposed Royal MAXX PRP Concentration System is substantially equivalent to the primary BioCUE Platelet Concentration Kit (BK100027). Differences between the proposed device and the primary predicate device have been assessed using FDA recognized voluntary consensus standards or methods consistent with that described in a prior 510(k) and differences in characteristics do not raise questions concerning safety or effectiveness. Based on the indications for use, technological characteristics, and tests performed, Royal Biologics has determined that the proposed Royal MAXX PRP Concentration System is substantially equivalent to the primary predicate device cleared via BK100027.