510(k) Summary

Device Trade Name:	**Royal MaxxPRP Concentration System**
Date:	April 16, 2018
Sponsor:	Royal Biologics LLC
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Sponsor:	Royal Biologics LLC. 50 Dey Street Jersey City, NJ 07306 Ph: 518-221-6932
Manufacturer:	Quality Tech Services, Inc. 10525 Hampshire Ave South Bloomington, MN 55438
Common Name:	Platelet and Plasma Separator for Bone Graft Handling
Device Classification:	Class II
Classification Name:	Automated Blood Separator
Regulation:	864.9245
Device Regulation Panel:	Hematology
Device Product Code:	ORG
Predicate Device:	GenesisCS Component Concentrating System (BK050055)

Device Description:

The Royal MaxxPRP Concentration System is a single-use, sterile kit consisting of syringes, transfer needle and concentrating device with other accessories as listed below. The concentrating device consists of a cylindrical container with a movable divider. It uses a standard centrifuge to separate platelets and plasma from whole blood and provides a means to capture platelet rich plasma (PRP) as a final product.

Specifically, the kit includes the following components:

- Royal MaxxPRP concentration device (1)
- 60cc syringe (1)
- 10 cc syringe (1)
- Alcohol wipes (2)
- 18-gauge blunt tipped needle (1)
- 12” drape (1)
- Anti-coagulant, 30mL bottle (1)

Additionally, Royal Biologics will make available non-sterile reusable accessories for use with the Royal MaxxPRP device including: a counter weight (for centrifuge counterbalance), scale, centrifuge buckets and knob that integrates with the movable divider of the concentration device.

Indications For Use:

The Royal MaxxPRP is designed to be used 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 to improve handling characteristics.

Comparison of Technological Characteristics with Predicate Device:

The fundamental scientific technology, processing methods and mechanism of operation are similar between the subject Royal MaxxPRP device and the predicate GenesisCS Component Concentration System (BK050055, cleared 10/13/2006– see comparison **Table 5-1** below) There are no technological characteristics that raise new issues of safety or effectiveness for how the PRP is generated compared with the GenesisCS device. Both the subject and predicate devices process 60cc of anticoagulated whole blood. Both devices require use of a centrifuge to separate the blood into layers based on cell density. The bottom layer generated is red blood cells (RBC) and above that is a buffy coat layer (white blood cells and platelets) and plasma. The buffy coat layer mixed with a small amount of plasma constitutes the final PRP product.

The technological difference between the operation of the Royal MaxxPRP and predicate devices is how the pressure difference is generated that separates the plasma and buffy coat layers from the RBC layer. The subject device uses a separator controlled by a lead screw, which the operator turns by hand. The movement of this separator creates a force (positive pressure) on the fluid that causes the plasma and buffy coat layer to move though a drawtube and into a holding chamber, which separates it from the RBC layer. The predicate uses suction from a syringe, controlled by the operator, to create a negative pressure on the plasma and buffy coat layer. This negative pressure causes the plasma and buffy coat layer to move into the syringe, which separates it from the RBC layer. The end result of the plasma and buffy coat layers being separated from the RBC layer by a pressure difference is substantially equivalent.

Table 5-1. Technological Characteristic Comparison

Point of Comparison	**Primary Predicate Device (GenesisCS Component Concentrating System - BK050055)**	**Subject Device Royal MaxxPRP**
Indications for use	The GenesisCS Component Concentrating System is designed for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic	The Royal MaxxPRP is designed to be used 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 to improve handling characteristics.

Table 5-1. Technological Characteristic Comparison

Point of Comparison	Primary Predicate Device (GenesisCS Component Concentrating System - BK050055)	Subject Device Royal MaxxPRP
	surgical site as deemed necessary by the clinical use requirements."	
System Components	Disposable concentrating device packaged with syringes, blood draw needles and blood draw accessories.	Disposable concentrating device packaged with syringes, aspiration needles, alcohol wipes and ACD-A anticoagulant.
Device Material	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices	Medical grade polymers, elastomers and stainless steel suitable for use in medical devices
Device Structure	Cylinder with internal piston	Same
Method of fluid separation	Centrifugation – separation of blood based on density	Same
Buffy coat layer isolation method	Aspiration of plasma and buffy coat through a piston, which moves in the container due to a pressure differential.	Displacement of plasma and buffy coat by a movable separator into a separate holding chamber in the device.
Centrifuge Device	General purpose centrifuge	General purpose centrifuge
Centrifugation Time and Speed.	The predicate device is spun one time in a centrifuge at 4400 RPM for 5 minutes.	The Subject device is spun two times in the centrifuge. The first spin is at 3500 RPM for 4 minutes, the second spin is at 3800 RPM for 5 minutes.
Sterile, Single-Use	Yes, Ethylene Oxide	Yes, Vapor Peracetic Acid

Performance Data / Non-clinical Tests:

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

Biocompatibility Testing:
Biocompatibility testing on the patient/fluid contacting materials of the device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Royal Maxx PRP concentrating device is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity (per ISO 10993-5), sensitization & intracutaneous reactivity (per ISO 10993-10), acute systemic toxicity (per ISO 10993-11), hemolysis testing (ASTM F756) and material-mediated pyrogenicity (ISO 10993-11).

Bench Testing:
A paired study evaluating PRP quality was conducted with the Royal MaxxPRP Concentration System and the predicate GenesisCS Component Concentrating System using blood collected from healthy human donors for processing into PRP. The following PRP quality tests were

performed: blood cell counts (platelets, erythrocyte cells, and leukocyte cells), platelet concentration factor, platelet yield, pH, platelet activation (resting and ADP stimulated), platelet aggregation, and hypotonic stress response. The results obtained demonstrate substantial equivalence of the Royal MaxxPRP System to the predicate device for all parameters evaluated.

Testing was conducted to determine if the platelet rich plasma (PRP) produced by the Royal MaxxPRP Concentrating System performs as indicated by improving bone graft handling. Testing involved analyzing the integrity of the composite clot formed when PRP produced by the device is mixed with allograft bone compared with saline as the control. The results obtained demonstrate that the device output retains bone graft material in a composite clot and the PRP produced by the device is superior to saline with respect to bone graft cohesion, and therefore, performs as indicated.

Shelf-Life/Device Integrity
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, simulated shipping and aging. The results demonstrated that the devices/packaging structural and functional integrity remain intact following conditioning and the data support a 1-year shelf-life for the device.

Pyrogenicity
The subject device has been tested for pyrogenicity and the presence of bacterial endotoxins on the device meets pyrogen limit specifications.

Sterilization Validation
The sterilization process used in the sterilization of the Royal MaxxPRP Concentrating System ((b) (4)) has been fully validated in accordance with *ANSI/AAMI/ISO 14937, Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.*

Conclusion:

Performance testing and comparison of characteristics between the subject and predicate device have demonstrated that the Royal MaxxPRP Concentration System is substantially equivalent to the predicate device with regard to intended use, operation, function, and technological characteristics.