510(k) Summary

I. SUBMITTER

Manufacturer: Royal Biologics Inc.
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II. DEVICE

Common Name:	Platelet and plasma separator for bone graft handling
Proprietary Name:	Royal Maxx™ Autologous 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 to which the Royal Maxx Autologous PRP Concentration System (APS) device is the Royal Maxx PRP Concentration System cleared via BK180204 (cleared July 12, 2018).

IV. DEVICE DESCRIPTION

The Royal Maxx Autologous PRP Concentration System is a sterile, single-use kit of consumables including a concentration device cleared under BK180204, accessories for blood collection and processing and ACD-A anticoagulant. The device is used with 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.

V. INDICATIONS FOR USE

The Royal Maxx Autologous PRP Concentration System 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 for mixing with autograft and/or allograft bone to improve handling characteristics.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Royal Maxx Autologous PRP Concentration System described herein is identical with that described in BK180204 with respect to indications for use, operational and performance characteristics. There has been no significant changes made to the PRP concentrator component. The purpose of this Special 510(k) is to describe modifications to the Royal Maxx Autologous PRP Concentration System with respect to packaging configuration, accessory components provided and change in sterilization method.

VII. PERFORMANCE DATA

The Royal Maxx Autologous 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.

Biocompatibility testing, packaging validation/shelf-life and device integrity testing were performed to assure that changes in sterilization method and packaging did not adversely alter the subject device and demonstrate that the modified device is substantially equivalent with the predicate.

VIII. CONCLUSION

The proposed Royal Maxx Autologous PRP Concentration System is substantially equivalent to the predicate as the basic design features and intended uses are the same. Differences between the proposed device and the predicate devices have been assessed using FDA recognized voluntary consensus standards and modified 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 predicate device cleared via BK180204.

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