510(k) Summary

I. Submitter

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II. Device Information

FDA Product Code:	PMQ
FDA Regulation Number:	21 CFR 864.9245
FDA Classification Name:	Automated Blood Cell Separator
Common Name	Peripheral Blood Processing Device for Wound Management
Classification Panel:	Hematology
FDA Classification:	Class II
Device Name:	RegenKit®-Wound Gel-2 (Ref. RK-BCT-2A WG)

III. Predicate Information

510(k) Number	Trade Name	Applicant
BK060007	AutoloGel System	Cytomedix

IV. Device Description

The RegenKit®-Wound Gel-2 permits autologous platelet rich plasma (PRP) and thrombin serum (ATS) to be rapidly prepared from a small volume of the patient's blood that is drawn at the time of treatment. Blood is collected directly into Regen™ BCT and Regen™ ATS vacuum tubes and then spun in a clinical centrifuge, according to centrifuge operating instructions. Under the supervision of a healthcare professional, PRP and ATS are prepared and combined with a 10% USP calcium solution (not supplied in the kit) to produce a PRP gel (RegenWound™ Gel), which is suitable for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers, and mechanically or surgically debrided wounds.

The RegenKit®-Wound Gel-2 produces approximately 13 ml of RegenWound Gel for use in the treatment of wounds, such as diabetic foot ulcers, classified up to 3A according to the University of Texas classification. The material produced will treat an approximate area of 0.62 +/- 0.49 cm^2 with a depth of 15.1 +/- 9.6 mm, or the equivalent.

V. Indication for Use

RegenKit-Wound Gel-2 is designed to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel (RegenWound Gel) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the RegenWound Gel is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds.

VI. Comparison of Technological Characteristics

The RegenKit-Wound Gel and the AutoloGel System are both designed for the preparation of PRP by simple centrifugation of a small sample of the patient's own blood. The subject and predicate devices are substantially equivalent based on the following similar technological elements:

- Phlebotomy with the provided blood collection set
- Automatic blood collection in evacuated tubes prefilled with citrate-based anticoagulant
- Blood component separation by centrifugation
- Liquid PRP collection
- PRP gel that is used as a wound dressing

A comparison of the subject and predicate device is provided in the following table.

Technological Characteristic	**Subject Device** RegenKit®-Wound Gel-2	**Predicate Device** AutoloGel System
A. Regulatory Information		
510(k) Number	BK210661	BK060007
Device Name	RegenKit-Wound Gel	AutoloGel™ System
Manufacturer	Regen Lab SA	Cytomedix, Inc.
Regulation Number	21 CFR 864.9245	21 CFR 864.9245
Device Class	Class II	Class II
Product Code	PMQ	PMQ

Technological Characteristic	Subject Device RegenKit®-Wound Gel-2	Predicate Device AutoloGel System
Classification Panel	Hematology	Hematology
B. Intended Use		
Indications for Use Statement	RegenKit®-Wound Gel-2 is designed to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel (RegenWound Gel, RWG) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the RegenWound Gel is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds.	The AutoloGel™ System is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient's own blood. Under the supervision of a healthcare professional, the PRP gel produced by the AutoloGel™ System is suitable for exuding wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and for the management of mechanically or surgically debrided wounds.
Prescription Status	Rx only	Rx only

C. Primary Technological Characteristics		
Kit Components	RegenKit-Wound Gel is supplied in one model RegenKit-Wound Gel-2 2 x Regen™ BCT tubes 1 x Regen™ ATS tube Required commercially available components, not supplied in the kits: 1 x Safety–Lok™ Butterfly needle 1 x Collection holder (blue top) 1 x Transfer device (pink top) 2 x 18G 1 ½ Red transfer needles 2 x 5 ml Luer-Lok™ syringes. Small sterile container, with a flat bottom, a maximal bottom surface of 30 cm^2 (4.6 in^2) and a minimal capacity of 15 mL (0.5 oz). Tube holder Accessories for phlebotomy and wound dressing including, but not limited to, tourniquet, sterile alcohol prep pads, sterile adhesive	The AutoloGel System Combination Kit consists of one AutoloGel System Wound Dressing Kit and one AutoloGel System Reagent Kit AutoloGel System Wound Dressing Kit: Tray 1 Phlebotomy: 1 Tourniquet 2 Sterile alcohol prep pads 6 Prefilled S-Monovette® syringe/tubes (5 mL) 1 Safety-Multifly® Set 2 Gauze sponges 1 Sterile adhesive bandages 1 Foam tube holder Tray 2 Processing and Application: 1 20mL mixing chamber, without needle 2 Sterile alcohol prep pads 2 Gauze sponges 1 5 mL syringe w/needle 1 3 mL syringe w/needle 1 Three-way stopcock 1 Blunt needle 1 N-Terface® Dressing 2 Skin Protectant Wipe 1 Towel/drape

Technological Characteristic	Subject Device RegenKit®-BCT Gel Family Kits	Predicate Device AutoloGel System
Reagent/s	Not supplied, required reagent: A USP 10% injectable solution of calcium - Calcium gluconate injection, USP 10% (100 mg/mL) Or Calcium chloride injection, USP 10% (100 mg/mL)	AutoloGel™ System Reagent Kit: - Thrombin topical (bovine origin), USP, 5,000 IU - Calcium chloride injection, USP 10 %, 100 mg/mL - Ascorbic acid injection, USP, 500 mg/mL
Blood collection tube	RegenBCT and RegenATS are 10 mL evacuated class I cerium III borosilicate glass tubes	S-Monovette® plastic tubes The vacuum for 5 mL is charged at the time of blood collection by pulling the Monovette plunger to full extension
Anticoagulant	USP 4 % Sodium citrate solution in RegenBCT tubes	Anticoagulant citrate dextrose solution-A (ACD-A) in S-Monovette® tubes
Blood separation medium	Thixotropic polymer gel with specific density in RegenBCT and RegenATS tubes	None
Centrifugation	Centrifugation at a relative centrifugal force of 1500 x g in a suitable general-purpose clinical centrifuge with swinging buckets or a 45° fixed angle rotor. - 5 minutes for RegenBCT tubes - 2 times 5 minutes for RegenATS tube	One-minute high speed centrifugation in preset AutoloGel™ System Centrifuge II
Kit sterilization	Full kit sterilized by Gamma irradiation	Kit assembly of sterile components
Shelf Life	24 months	24 months

Regen Lab has demonstrated that the difference in the technological characteristics of the subject and predicate device does not raise new questions of safety or effectiveness.

VII. Summary of Non-Clinical Testing and Risk Analysis

Biocompatibility Testing

Various studies were conducted in accordance with the FDA guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Hemocompatibility
- Rabbit Pyrogen study

The components of RegenKit-Wound Gel are considered blood contacting (either circulating blood or indirect blood path) for a duration of less than 24 hours.

Performance Testing

Non-clinical bench tests to evaluate performance of Regen BCT tube for PRP preparation, including pH, blood cell count, platelet recovery, platelet concentration factor, platelet integrity and functionality, and performance of RegenATS tube regarding the preparation of a serum containing autologous thrombin, were conducted to characterize effectiveness of subject device in the preparation of autologous PRP gel. Additionally, a gel characterization (moisture content, clot strength, shear strength, gel stiffness) was performed. In all instances, the RegenKit-Wound Gel worked as intended and the performances observed were as expected and considered equivalent to the performance of predicate device.

VIII. Clinical Testing

A summary from a single-center, open-label, randomized, controlled clinical trial performed by Regen Lab to evaluate the efficacy of the autologous platelet gel as compared to the standard of care treatment of diabetic foot ulcers (DFU) was provided with this submission. The trial enrolled subjects with type 1 and type 2 diabetes mellitus, with one or more grade 3A DFUs (University of Texas DFU Classification), with wound surface area up to 5 cm^2.

Ninety-one subjects (ITT population) were treated (47 in RWG group, 44 in control group) at inclusion visit. Majority of subjects (65/91) presented with a "pertuis" (deep ulcers with a small orifice), in which the wound surface area of the ulcer was not measured. In the other subjects (26/91), the mean wound surface area was 0.62 cm2 at the screening (SV) for the RWG group, and 0.77 cm2 for the control group. The results of the study showed that at Week 12, the DFU closure rate was 77.3% in the RegenKit-Wound Gel (RWG) group, compared to 35.1% in the control group. The average DFU closure time was 39 days in the RWG group and 46 days in the control group. The treatment was well tolerated.

IX. Conclusion

Based on the comparison of intended use and technological characteristics, Regen Lab has demonstrated that the RegenKit-Wound Gel-2 is substantially equivalent to the predicate device and is safe and effective for its intended use.