

## 510(k) Summary

### DATE PREPARED

27 May 2025

### MANUFACTURER AND 510(k) OWNER

**Manufacturer:** Royal Wound-X, Inc.  
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### DEVICE INFORMATION

Proprietary Name/Trade Name: PRF-Matrix System  
Common Name: Peripheral blood processing device for wound management  
Regulation Number: 864.9245  
Class: II  
Product Code: PMQ  
Review Panel: Hematology

### PREDICATE DEVICE IDENTIFICATION

| 510(k) Number | Predicate Device Name / Manufacturer           | Predicate/Reference |
|---------------|--|---------------------|
| BK060007      | Cytomedix/ Autologel System                    | Predicate           |
| BK120008      | Royal Biologics/Fibrinet Autologous PRP System | Reference           |

The predicate devices have not been subject to a design related recall.

## **DEVICE DESCRIPTION**

### **1. Overview**

The PRF-Matrix system is intended to be used for the safe and rapid preparation of platelet-rich gel from a small sample of a patient's own peripheral blood at point-of-care. Under the supervision of a healthcare professional, the platelet-rich plasma (PRP) gel produced is topically applied for the management of cutaneous wounds such as diabetic ulcers, venous leg ulcers, and mechanically or surgically debrided wounds.

The PRF-Matrix System is designed to be used for the management of chronic wounds for up to twelve weeks if the wound does not show improvement with 2 or more weeks of standard of care treatment, as determined by a licensed health care practitioner.

The PRF-Matrix System should be used in conjunction with standard of care procedures for comprehensive wound management such as the removal of necrotic or infected tissue, cleansing the wound, maintenance of a moist wound environment, off-loading, management of infections of the wound, proper nutrition, blood glucose control for subjects with diabetic ulcers, and management of any underlying disease that may be contributing to the wound.

The PRF-Matrix System is a sterile, single-use kit of consumables including:

*PRF-Matrix System custom products:*

- Four (4) PRP tubes (indicated by a yellow stopper)
- Two (2) PRFM Membrane Vials

*The legally marketed devices in the kit include:*

- Two (2) (female)Luer-Lok transfer devices (indicated by a red tip)
- Two (2) (male) Luer-Lok access devices (indicated by a blue tip)
- One (1) 20mm vial adapter
- One (1) Safety-wing blood collection set
- One (1) Latex-free tourniquet

### **INDICATIONS FOR USE**

The PRF-Matrix system is intended to be used for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient's own peripheral blood at point-of-care. Under the supervision of a healthcare professional, the PRP gel produced is topically applied for the management of cutaneous wounds such as diabetic ulcers, venous leg ulcers, and mechanically or surgically debrided wounds.

### **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

Royal Wound-X, Inc. believes that the PRF-Matrix System is substantially equivalent to the predicate devices based on the information summarized here:

**Table 1. Substantial Equivalence of PRF-Matrix System to Predicate, Autologel**

|  | <b>Subject Device</b>  | <b>Predicate Device</b>  |                   |
|--|--|--|-------------------|
|  | <b>Royal Wound-X, Inc.<br/>PRF-Matrix System</b>   | <b>Cytomedix<br/>Autologel System<br/><br/>BK060007</b>  | <b>Discussion</b> |
| <b>Indications for Use</b>               | The PRF-Matrix system is intended to be used for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient’s own peripheral blood at point-of-care. Under the supervision of a healthcare professional, the PRP gel produced is topically applied for the management of cutaneous wounds such as diabetic ulcers, venous leg 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.<br>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 | Same              |
| <b>Product Codes / Regulation Number</b> | PMQ (Peripheral blood processing device for wound management)<br>864.9245  | PMQ (Peripheral blood processing device for wound management)<br>864.9245  | Same              |
| <b>Regulation Description</b>            | Automated blood cell separator   | Automated blood cell separator   | Same              |
| <b>Prescription Status</b>               | Rx Only  | Rx Only  | Same              |
| <b>Components</b>                        | Table top centrifuge (Drucker DASH FLEX 24 Centrifuge)<br>PRF-Matrix System kit components:: <ul style="list-style-type: none"> <li>PRP tube (x4): 10 mL PET evacuated blood collection tube containing (b) (4) buffered tri-sodium citrate and separator gel</li> <li>containing (b) (4) CaCl<sub>2</sub></li> <li>Membrane Vial (x2): 30 mL</li> </ul>   | <ul style="list-style-type: none"> <li>Table top centrifuge (AutoloGel II Centrifuge)</li> <li>Wound dressing convenience kit (AutoloGel Wound Dressing Kit) comprised of legally-marketed products, i.e., blood access and processing devices, USP-grade reagents (ascorbic acid, bovine thrombin, calcium chloride and ACD-A anticoagulant)</li> </ul>   | Equivalent        |

|                                     |   |   |            |
|-------------------------------------|---|---|------------|
|                                     | glass vial containing (b) (4)<br>(b) (4) USP grade (b) (4) CaCl <sub>2</sub><br>Legally marketed devices: <ul style="list-style-type: none"> <li>• Blood collection set</li> <li>• Luer adapter, male</li> <li>• Luer adapter, female</li> <li>• Vial adapter</li> <li>• Latex-free tourniquet</li> </ul> |   |            |
| Source material for PRP gel         | Patient's own blood   | Patient's own blood   | Same       |
| Anti-coagulant                      | Buffered tri-sodium citrate   | ACD-A anticoagulant   | Equivalent |
| Coagulation reagent                 | Calcium chloride (CaCl <sub>2</sub> )   | Ascorbic acid, bovine thrombin, calcium chloride (CaCl <sub>2</sub> )   | Equivalent |
| Device output to be used on patient | PRP gel   | PRP gel   | Same       |
| Anatomical location of use          | Wounds such as diabetic ulcers, venous leg ulcers, and mechanically or surgically-debrided wounds.  | Wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds | Same       |
| Mode of Use                         | Topical application to wound  | Topical application to wound  | Same       |
| Sterility                           | Sterile   | Sterile   | Same       |
| Shelf -Life                         | 2 years   | 2 years   | Same       |

The subject device has the same intended use/indications for use as the predicate device. The PRF-Matrix System (subject device) and the proposed predicate devices are both intended to be used at point-of-care for the safe and rapid preparation of a PRP gel from a small sample of a patient's own peripheral blood. Both systems use peripheral blood to create autologous gels suitable for use in cutaneous wounds.

The PRF-Matrix System and the predicate device, Autologel (BK060007) are based on the same general technological characteristics.

- Both systems include a single use medical device kit to prepare, at point-of-care, an autologous gel from the patient's own peripheral blood.
- Both systems create autologous blood-based gels suitable for use in covering cutaneous wounds.
- Both systems use blood collection tubes to collect a patient's whole blood at point of care. The tubes of both systems are centrifuged to separate the whole blood and isolate liquid PRP.
- Both systems use additional processing steps to convert the liquid (PRP) into a PRP gel that is suitable for use in covering the patient's cutaneous wounds. (Autologous use)
- Both systems use similar single-use, disposable blood drawing components.
- Both systems are used with a centrifuge.

## **SUMMARY OF NON-CLINICAL TESTING**

The following tests were performed to demonstrate safety based on current industry standards:

**Biocompatibility:** Biocompatibility assessment was conducted per ISO 10993-1: 2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system*.

**Performance Testing:** Performance testing was conducted to evaluate the performance of the PRF-Matrix System in comparison to Autologel (BK060007). The following performance characteristics were evaluated:

- Moisture Content
- Tensile Testing
  - Clot Strength (Maximal Break Force)
  - Shear Strength (percent elongation before 1st tear)
  - Gel Stiffness
- Hematology
  - Cell Recovery – Platelets
  - Cell Recovery -White Blood Cells (WBC)
  - Cell Recovery -Red Blood Cells (RBC)

In all instances, the PRF-Matrix System worked as intended and the performances observed were as expected and considered equivalent to the performance of predicate device.

**Sterilization:** Sterilization of the PRFM vial by moist heat, prior to packaging, sterilization of the tube set by gamma irradiation and sterilization of the tray assembly by ethylene oxide is supported by sterilization validation and testing as well as package integrity testing, conducted in accordance with FDA recognized consensus standards.

**Shelf-Life:** The shelf-life of the PRF-Matrix System (2 years) is supported by accelerated aging testing conducted in accordance with ASTM F1980.

The results of these tests indicate that the PRF-Matrix System is substantially equivalent to the predicate devices.

## **SUMMARY OF CLINICAL TESTING:**

Clinical efficacy studies were performed externally at two sites. An observational prospective, efficacy study of patients with lower-extremity ulcers and a single-arm, open-label prospective safety and efficacy study of patients with diabetic foot ulcers were conducted to evaluate the safe and effective use of the PRF-Matrix System for the safe and rapid preparation of PRP gel from a small sample of a patient's own peripheral blood at point-of-care to produce a PRP gel to be topically applied for the management of cutaneous wounds such as diabetic ulcers, venous leg ulcers, and mechanically or surgically debrided wounds.

Test results demonstrated the safe and effective use of the PRF-Matrix System for its intended use.

## **CONCLUSION**

Based upon the comparison of the labeling and the technological and functional characteristics, the information provided in this submission – including results from risk assessments and testing activities related to performance and usability/human factors – demonstrates that the subject PRF-Matrix System device functions as intended and is substantially equivalent to the predicate device. Differences between the subject and predicate devices do not raise any different questions about safety or effectiveness. Therefore, the proposed device, PRF-Matrix System is substantially equivalent to the predicate device (BK060007).