**510(k) SUMMARY**
**For**
**SkinDisc™ Lite - Wound System and the SkinDisc™ - Wound System**

## Submitter Information:

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## 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: | SkinDisc Lite; SkinDisc |

| **Predicate Device Name** | **510(k)** | **Company Name** |
|---|---|---|
| REGENKIT-Wound Gel-2 | BK210661 | RegenLab SA |
| **Reference Device Name** | | |
| Plasmax Plasma Concentrator with GPS® II Mini Platelet Concentrate Separation Kit With ACD-A | BK070003 (Special) | Biomet Biologics, Inc. |
| Plasma Concentrator<br>GPS® III Mini Platelet Concentrate Separation Kit With ACD-A, GPS® III Platelet Concentrate Separation Kit With ACD-A, GPS® III Platelet Concentrate | BK050016<br>BK070026 (Special) | Biomet Biologics, Inc. |

## Description of Device:

SkinDisc™ and SkinDisc™ Lite– Wound Systems are single use medical devices used to rapidly prepare a platelet rich plasma (PRP) and platelet poor plasma (PPP) from a small volume of the patient's own peripheral blood that is drawn at the time of treatment. The device kit consists of a disposable separator and accessories to be used with a table-top, swinging bucket centrifuge.

The PRP and PPP are obtained by density using the Zimmer-Biomet centrifuge, according to centrifuge operating instructions. Under the supervision of a healthcare professional, PRP and PPP are prepared and combined with commercially available Calcium Chloride Thrombin (not supplied in the kit) to produce (SkinDisc™/SkinDisc™Lite) which are suitable for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers, and mechanically or surgically debrided wounds.

The SkinDisc™ Wound System contains a Plasmax Plus Plasma Concentrator (60ml), a GPS® III Platelet Concentrate Separation Kit, ACD-A and blood draw components. 60ml of blood produces approximately ~26 ml of SkinDisc for use in the treatment of wounds.
The SkinDisc™ Lite – Wound System contains a Plasmax Plasma Concentrator (30ml), a GPS® III Mini Platelet Concentrate Separation Kit, ACD-A and blood draw components. 30ml of blood produces approximately ~13 ml of SkinDisc for use in the treatment of wounds.

## Intended Use/Indications For Use:

The SkinDisc™ Wound System is designed to be used at point-of-care for the safe and rapid preparation of platelet rich plasma (PRP) and platelet poor plasma (PPP), from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the SkinDisc™ 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.

## Comparison of Technological Characteristics:

SkinDisc™ Wound Systems and the predicate device 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:

- All are used at the patients point of care to separate and prepare autologous blood, blood fractions in a single procedure to be used clinically
- All separate blood/blood components by centrifugation/density.
- Similar blood volumes are used/Similar blood component gel volumes produced.
- All are based on phlebotomy with the provided blood collection set.
- Liquid PRP collection)
- PRP gel that is used as a wound management dressing
- Same indications for use statements.

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

| Technological Characteristic | Subject Device: SkinDisc System | Predicate Device: RegenKit WG-2 |
|---|---|---|
| **Regulatory Information** | | |
| **510(k) Number** | BK241079 (new) | BK210661 |
| **Device Name** | SkinDisc Lite; SkinDisc | RegenKit – Wound Gel - 2 |
| **Manufacturer** | Innoveren Therapeutics | Regen Lab SA |
| **Regulation Number** | 21 CFR 864.9245 | 21 CFR 864.9245 |
| **Device Class** | Class II | Class II |
| **Product Code** | PMQ | PMQ |
| **Classification Panel** | Hematology | Hematology |
| **Intended Use** | | |
| **Indications For Use** | The SkinDisc™ Wound System is designed to be used at point-of-care for the safe and rapid preparation of platelet rich plasma (PRP) and platelet poor plasma (PPP), from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the SkinDisc™ 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. | 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 Regen Wound 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. |
| **Prescription Status** | Rx | Rx |
| **Primary Technological Characteristics** | | |
| **Kit Components** | **Supplied: SkinDisc System:**<br>GPS III Separator<br>Plasma Concentrator<br>60ml syringe<br>10ml syringe | **Supplied: RegenKit-Wound Gel-2**<br>2 x Regen™ BCT tubes 1 x Regen™ ATS tube |

| | | |
|---|---|---|
| | 18Ga needle set<br>Adhesive tape<br>Alcohol pads<br><br>***Required commercially available components, not supplied in the kits:***<br>Small sterile container, with a flat bottom, and a minimal capacity of 15 mL (0.5 oz) | <br><br><br><br>***Required commercially available components, not supplied in the kits:***<br>Small sterile container, with a flat bottom, and a minimal capacity of 15 mL (0.5 oz).<br>Tube holder<br>Accessories for phlebotomy and wound dressing including, but not limited to, tourniquet, sterile alcohol prep pads, sterile adhesive<br>1 x Safety–Lok™ Butterfly needle 1 x Collection holder (blue top)<br>1 x Transfer device (pink top)<br>2 x 18G 1 ½ Red transfer needles 2 x 5 ml Luer-Lok™ syringes. |
| **Reagents** | ***Not supplied:***<br>USP Calcium Chloride Thrombin 10% | ***Not supplied:***<br>USP Calcium Gluconate 10%<br>or<br>USP Calcium Chloride 10% |
| **Blood Collection** | The GPS III Platelet Separator - 1x medical grade polymer tube<br>The Plasma Concentrator – 1x medical grade polymer tube (with porous polyacrylamide desalting beads). | Regen BCT – 2 x class 1 cerium III borosilicate glass tubes<br>Regen ATS tube (with coagulant). 1x class 1 cerium III borosilicate glass tube |
| **Anticoagulant** | 30ml bottle ACDA | 4% sodium citrate solution |
| **Centrifugation** | Zimmer Biomet Centrifuge<br>15 mins x 3200 rpm for PRP/PPP<br>2 minutes x 2000 rpm for PPPc | Suitable clinical centrifuge with swinging buckets<br>5 minutes x 1(500 x g) for PRP (BCT tubes)<br>Up to 2 x 5 minutes for PPP / PPPc (ATS tubes) |
| **Kit Sterilization** | Kit assembly of sterile components | Sterilized by Gamma irradiation |
| **Shelf Life** | 24 months | 24 months |

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

**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 SkinDisc™ Systems 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 the SkinDisc system was conducted, including, cell recovery efficiency (i.e., red blood cell count, white blood cell count, platelet count), moisture content, clot visual examination and clot handling characteristics. In all instances, the SkinDisc Systems worked as intended and the performances observed were as expected and considered equivalent to the performance of predicate device.

**Clinical Testing:**

A summary from a single center, open label, randomized controlled clinical trial was performed and provided in this submission to evaluate the safety and efficacy of the autologous platelet gel as compared to standard of care treatment of diabetic foot ulcers (DFU). The trial enrolled subjects with type 1 and type 2 diabetes mellitus with one or more DFUs with a wound surface area up to 25cm$^2$
19 subjects were treated (10 in SDL treatment Group and 9 in SOC control group). The results of the study showed that at week 12 the DFU % reduction in ulcer size was 100% in the SkinDisc treatment group compared to 49.2% in the SOC control group. The average DFU closure time was 8.5 weeks in the SkinDisc treatment group with only 1 patient achieving closure by 12 weeks in the SOC control group. The SkinDisc device was well tolerated, with no treatment-related adverse events.

**Conclusion Regarding Substantial Equivalence:**

The SkinDisc™ Systems have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the predicate devices, use similar material and energy sources, and have a similar design as the predicate devices.

Based on this, Innoveren has demonstrated that the SkinDisc System is substantially equivalent to the predicate device and is safe and effective for its intended use.