Section 7: 510(k) Summary

510(K) SUMMARY
RedDress Ltd.'s RD2 Ver.02 System

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Date Prepared: March 24, 2021

Name of Device (Trade Name): RD2 Ver.02 System

Common or Usual Name:
Peripheral blood processing device for wound management

Classification Regulation:
21 CFR 864.9245 (Automated blood cell separator)

Regulatory Class: II

Product Code: PMQ

Predicate Device: RedDress Ltd.'s RD2 System (BK200464)
Reference Devices: RedDress Ltd.'s RD1 System (BK170095)
Beijing Hanbaihan Medical Devices Co., Ltd's Healon PRP tubes (BK170136)

Device Description:
The RD2 Ver.02 System is a "convenience kit" that contains the following components for drawing and handling autologous whole blood and allowing it to clot in a controlled manner in order to form a wound matrix/dressing:

1. Blood withdrawal kit
2. Clotting tray containing coagulation initiator and coagulation accelerator
3. Wound dressing components

To use the kit, 15ml of blood from the patient is drawn into a sterile vacuum tube containing ACD-A anticoagulant. Subsequently, the citrated blood is injected into a sterile coagulation mold (clotting tray) – which contains cotton gauze, calcium gluconate powder (coagulation initiator), and Kaolin powder (coagulation accelerator), to coagulate for 8 minutes. The whole blood clot that is formed is then extracted using the supplied clot extraction ring, placed on the patient's wound, and dressed with a secondary sterile non-adherent dressing. All RD2 Ver.02 System kit elements and reagents are disposed of after a single use of the kit. The procedure may be repeated with a new RD2 Ver.02 System kit after a few days.

The components of the RD2 Ver.02 System that are manufactured by RedDress are sterilized together in the Large Tray; subsequently, this Tray is packaged with the off-the-shelf components in a non-sterile outer package, as the final system kit.

Intended Use / Indications for Use:

The RD2 Ver.02 System is intended to be used at point-of-care for the safe and rapid preparation of Whole Blood Clot (WBC) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the WBC produced by the RD2 Ver.02 System is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanically or surgically-debrided wounds.

The intended use of the device is the same as that of the predicate. There is no substantive difference in indications for use; the device name has been updated and the word "gel" has been removed to better reflect the appearance of the clot material.

Summary of Technological Characteristics:

Both the RD2 Ver.02 System and the RD2 System kits are designed to allow healthcare professionals to safely prepare a whole blood clot from a small sample of the patient's own blood. The kits contain the same types of components to implement each step of the clot formation. All kit components are single-use, and there is no processing or manipulation of the blood.

The subject and predicate devices are fundamentally the same in terms of design, technology, and principles of operation. The subject device incorporates minor changes in the formulation/form of certain reagents, with updates to the preparation of reagents (*i.e.,* their relative proportions) in order to produce equivalent output. The table below compares the key features of the two systems.

	RD2 Ver.02 System (Subject Device)	RD2 System (Predicate Device K200464)
Intended Use / Indications for Use	The RD2 Ver.02 System is intended to be used at point-of-care for the safe and rapid preparation of Whole Blood Clot (WBC) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the WBC produced by the RD2 Ver.02 System is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanically or surgically-debrided wounds.	The RD2 System is intended to be used at point-of-care for the safe and rapid preparation of Whole Blood Clot (WBC) gel from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the WBC gel produced by the RD2 System is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanically or surgically-debrided wounds.
Clotting tray / coagulation mold	Single size, PETG (manufactured by RedDress)	Single size, PETG (manufactured by RedDress)
Anticoagulant Reagent	ACDA (manufactured by Beijing Hanbaihan Medical Devices Co., Ltd))	ACDA (manufactured by Becton Dickinson)
Calcium Gluconate (CG) Reagent	Calcium gluconate in a powder form; supplied in coagulation mold	Calcium Gluconate solution; supplied separately and added by the user to coagulation mold
Kaolin reagent	Supplied sterile in coagulation mold	Supplied sterile in coagulation mold

	ℝD2 Ver.02 System (Subject Device)	ℝD2 System (Predicate Device 𝔹K200464)
ℝeagents Titration	Blood: 15ml ACD-A: 1.5ml CG: 85mg (powder) Kaolin: 28mg	Blood: 15ml ACD-A: 3.4ml CG: 352.8 mg in 3.6ml solution Kaolin: 28mg
Size of Final WBC	Diameter: 6 cm Area: 28.3 cm^2	Diameter: 6 cm Area: 28.3 cm^2

Performance Data:

The RD2 Ver.02 System components were subjected to in vitro testing, with results demonstrating that the device is safe for use in handling blood.

The RD2 Ver.02 System coagulation mold with cotton gauze, calcium gluconate and Kaolin was subjected to the following tests in its final sterile, packaged configuration:

- Performance validation
- Physico-chemical validation
- Sterility validation
- Bioburden validation
- Endotoxin (LAL) validation
- Shelf life validation
- Shipping Simulation Validation
- Biocompatibility testing per ISO 10993-1 and FDA's guidance
- USP testing of ACD-A and calcium gluconate reagents

The RD2 Ver.02 System kit was subject to the following tests in its final packaged configuration:

- Packaging validation
- Sterility validation
- Bioburden validation
- Endotoxin (LAL) validation
- Shelf life validation
- Shipping Simulation Validation

The company also performed the following additional biocompatibility tests on the reagent mixture (kaolin, ACDA, calcium gluconate, and gauze):

- Cytotoxicity Study Using the ISO Elution Method
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- USP Pyrogen Study – Material Mediated
- ISO Acute Systemic Toxicity Study in Mice
- ISO Sub-chronic Toxicity Dual Routes of Parenteral Administration with Histopathology, Clinical Chemistry & Hematology 14 Day Rats
- ISO Muscle Implantation Study in Rabbits - 2 Weeks
- ISO Muscle Implantation Study in Rabbits - 4 Weeks

In addition, the company performed bench testing on the final RD2 Ver.02 System as a whole, to confirm that it functions per its specifications. The device functioned as intended and all

results were passing.

The RD2 Ver.02 System was subjected to physico-chemical testing, identical to the physico-chemical testing performed for the predicate device, to compare the outputs of the two devices. The results demonstrated that the whole blood clot output of the RD2 Ver.02 System is substantially equivalent to that of the predicate.

The RD2 Ver.02 System differences from RD2 raise no risk that requires additional animal or clinical testing. The animal and clinical testing performed in support of the RD1 System (originally cleared version of the device) remains applicable to the subject device, as further support of the subject device's safety and effectiveness given the similarities between the products.

Conclusion:

The RD2 Ver.02 System has the same intended use and indications for use, and very similar technological characteristics and principles of operation, as its predicate device. The minor technological differences between the RD2 Ver.02 System and its predicate raise no new questions of safety or effectiveness, because they do not alter how the device is used, its intended clinical effect, or the fundamental composition or performance of its output. Performance and physico-chemical data on the RD2 Ver.02 System further demonstrate that the subject device is as safe and effective as the predicate. Thus, the RD2 Ver.02 System is substantially equivalent to the RD2 System.