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

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Name of Device (Trade Name): RD2 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 RD1 System (BK170095)

Reference Device: Cytomedix, Inc.'s Autologel (BK060007)

Device Description:
The RD2 System is a "convenience kit" that contains 3 components for drawing and handling autologous blood and allowing it to clot in a controlled manner in order to form the provisional wound matrix (preparation kit):

1. Blood withdrawal kit
2. Coagulation initiator component
3. Clotting tray containing coagulation accelerator

The device includes an Instructions for Use manual detailing the different steps and materials for preparation of the whole blood clot wound care dressing.

Intended Use / Indications for Use:
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.

There is no difference in intended use or indications for use (except the device name) between the RD2 System and its predicate device, the RD1 system.

Summary of Technological Characteristics:

The RD2 System kit is designed to allow healthcare professionals to safely prepare a whole blood clot from a small sample of the patient's own blood. All RD2 System kit components are single-use, and there is no processing or manipulation of the blood.

To use the kit, blood is drawn into two (2) 8.5-9.5 ml user-supplied sterile vacuum tubes containing anticoagulant (ACDA). The citrated blood is then drawn into a 30ml syringe and is gently mixed with calcium gluconate. The coagulating blood is placed in a sterile coagulation mold containing cotton gauze and Kaolin powder, which accelerates the coagulation process, to coagulate for 12 minutes. Afterward, the whole blood clot is extracted using the supplied clot extraction ring, placed on a wound, and dressed with a secondary sterile non-adherent dressing. All RD2 System kit elements and reagents are disposed of after a single use of the kit. The procedure may be repeated with a new RD2 System kit after a few days.

The subject and predicate devices are fundamentally the same in terms of design, technology, and principles of operation; the main differences are outlined in the following table:

	RD2 System (Subject Device)	RD1 System (Predicate Device BK170095)
Anticoagulant Reagent	Citrate Anticoagulant (user-supplied ACDA, not a device component)	Citrate Anticoagulant; CPDA1 drawn from blood bag
Kaolin Powder Reagent	Sterilized by (b) (4); provided already in coagulation mold	Sterilized by (b) (4) ; separately added to coagulation mold
Clotting tray/ Coagulation Mold	Single size, PETG manufactured by RedDress	Multi sizes, off the shelf boxes
Reagents Titration	Blood: 15ml Citrate Anticoagulant: (b) (4) Calcium Gluconate: 3.6ml Kaolin: 28mg	Blood: 10ml Citrate Anticoagulant: (b) (4) Calcium Gluconate: 2ml Kaolin: 12mg
Size of Final WBC Clot	Diameter: 6cm Area: 28.3 cm^2	Diameter: 4.7cm Area: 17.4cm^2

Performance Data:

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

The RD2 System Coagulation Mold with cotton gauze and Kaolin manufactured by RedDress was subjected to the following tests in its final sterile, packaged configuration (and employing two 8.5-9.5 ml ACDA tubes):

- Performance validation
- Physico-Chemical validation (with ACDA tubes and RedDress-manufactured calcium gluconate)
- Sterility validation
- Bioburden validation
- Endotoxin (LAL) validation
- Shelf life validation
- Shipping Simulation Validation
- Biocompatibility testing per ISO 10993-1 and FDA's guidance

The RD2 System sterile Calcium Gluconate vial manufactured by RedDress was subjected to the following tests in its final sterile, packaged configuration:

- Performance validation
- Physico-Chemical validation (with user-supplied ACDA tubes, coagulation mold and kaolin)
- Sterility validation
- Bioburden validation
- Endotoxin (LAL) validation
- Shelf life validation
- Shipping Simulation Validation
- (b) (4) testing

The RD2 System kit manufactured by RedDress was subjected 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.

Reagent mixture (kaolin, user-supplied ACDA, *calcium gluconate, and gauze):*

- Cytotoxicity Study Using the ISO (b) (4)
- ISO Intracutaneous Study in Rabbits
- (b) (4) Pyrogen Study – Material Mediated
- ISO Acute Systemic Toxicity Study in Mice
- ISO Guinea Pig Maximization Sensitization Test
- 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

Non-adherent pad and Absorbent foam dressing (each separately):
- Cytotoxicity Study Using the ISO (b) (4)
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization

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

Each component of the RD2 System is separately sterilized and packaged, and then all components are placed together in a non-sterile outer package.

The RD2 System was subjected to physico-chemical testing, identical to that performed for the RD1 System predicate device, in order to compare the outputs of the two devices. The results demonstrated that the RD2 System is substantially equivalent to the predicate RD1 System.

The RD2 System differences from RD1 raise no risk that requires additional animal or clinical testing beyond that performed in support of the RD1 System, which remains applicable as further support of the subject device's safety and effectiveness given the similarities between the two products.

Conclusion:

The RD2 System is as safe and effective as the RD1 System. The RD2 System has the same intended use, indications for use, and principles of operation, as well as very similar technological characteristics, as its predicate device. The minor technological differences between the RD2 System and its predicate device 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 System further demonstrate that the subject device is as safe and effective as the predicate. Thus, the RD2 System is substantially equivalent to the predicate device.