510(k) #:

510(k) Summary

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Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	FastSkin Patch
Common Name	Peripheral Blood Processing Device for Wound Management.
Classification Name	Automated Blood Cell Separator
Regulation Number	864.9245 (Regulatory Class II)
Product Code(s)	PMQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
BK210570	ActiGraft® RD2 Ver.02 System	PMQ

Device Description Summary

21 CFR 807.92(a)(4)

The FastSkin® Patch 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:

The FastSkin® Patch includes:

- Blood Management Kit
- Coagulation Cartridge
- Coagulation Initiator
- Patient Labels
- Instruction of Use

The Blood Management Kit includes a blood collection set which is used to collect and store the patient’s blood prior to preparation of the whole blood clot.(WBC).

The following additional accessories (not included in the kit) are required for the use of the FastSkin® Patch:

- Calcium gluconate 100 mg mL Preservative-free single-dose bottle 10 mL (Rx)
- Sterile gloves, Nitrile Powder-Free
- Sterile alcohol pad
- Sterile Non-adherent dressing / Gauze pad

To use the kit, 20 mL of blood from the patient is drawn into two sterile vacuum tubes containing ACD-A anticoagulant. Calcium gluconate solution is injected into the kaolin vial and mixed. This suspension and the citrated blood are then gently mixed and added to the sterile coagulation cartridge to coagulate for 8 minutes. The whole blood clot that is formed is then transferred to a non-adherent dressing and applied to the patient's wound. All FastSkin Patch kit elements and reagents are disposed of after a single use of the kit. The procedure may be repeated with a new FastSkin Patch kit after a few days.

Off-the-shelf component packages are individually sterile. The coagulation cartridge is sterilized via (b) (4) and the coagulation initiator vial is sterilized via (b) (4) and packed in a non-sterile pouch bag. All components are then packed in a non-sterile cardboard carton as the final kit.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Fast Skin Patch 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 FastSkin Patch 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.

Technological Comparison

21 CFR 807.92(a)(6)

The FastSkin Patch and ActiGraft RD2 Ver.02 System are both designed to allow healthcare professionals to safely prepare a whole blood clot from a small sample of the patient's own blood.

The subject and predicate devices are substantially equivalent based on the following similar elements:

- All kit components are single-use
- All are based on phlebotomy with the provided blood collection set
- Automatic blood collection in sterile vacuum tubes containing ACD-A anticoagulant
- Mixing with calcium gluconate and kaolin to coagulate
- There is no processing or manipulation of the blood
- Similar blood volumes are used and similar whole blood clot volumes are produced
- Whole blood clot formed is used for topical management of wounds
- Same indications for use statement

The table below compares the key features of the two systems:

Device	Subject Device	Predicate Device
Trade Name	FastSkin® Patch	ActiGraft® RD2 Ver.02 System
Applicant	MimiX Biotherapeutics Ltd	RedDress Ltd
510(k) Number	BK251174 (New)	BK210570
Classification Product Code	PMQ	PMQ
Device Class	Class II	Class II
Regulation Number	21 CFR 864.9245	21 CFR 864.9245

Intended Use Indications for Use	The FastSkin® Patch is intended to be used at the 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 FastSkin® Patch 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 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.
Coagulation Cartridge / Mold	Single size sterile PETG sealed with Tyvek cover inside Polyamide- Polyethylene (OPA-PE) pouch	Single size sterile PETG sealed with Tyvek cover
Anticoagulant Reagent	ACDA (manufactured by Beijing Hanbaihan Medical Devices Co., Ltd)	ACDA (manufactured by Beijing Hanbaihan Medical Devices Co., Ltd)
Coagulation Reagents	Kaolin supplied sterile in 4ml vial Calcium Gluconate solution *(not supplied in kit)*	Kaolin supplied sterile in coagulation mold Calcium Gluconate powder supplied in coagulation mold
Blood management kit	Tourniquet, 18" length Sterile blood collection set, 21G winged with 7" Tube with holder 2 sterile ACD-A vacuum tubes, each containing up to 10 mL for blood collection 30 mL sterile syringe 5 mL sterile syringe for coagulation initiator mixing. 18 G safety needle - for coagulation initiators transfer 18 G safety needle - for blood injection	Tourniquet, 18" length Sterile blood draw/infusion set, 21G winged with 7" Tube with holder Sterile alcohol pad 2" x 2" Gauze pad Bandage Sterile gloves, Nitrile Powder-Free Sterile alcohol pad Sterile Non-adherent dressing / Gauze pad
Blood Draw	20mL	15mL
Reagent Titration	Blood: 20ml ACD-A: 1.0ml within vacuum tube CG: 360mg in 3.6ml solution (10%) Kaolin: 28mg	Blood: 15ml ACD-A: 1.5ml within vacuum tube CG: 85mg powder Kaolin: 28mg
Operation	20 mL of blood from the patient is drawn into two sterile vacuum tubes containing ACD-A anticoagulant. Calcium gluconate solution is injected into the kaolin powder vial and mixed. This suspension and the citrated blood are then gently mixed and added to the sterile coagulation cartridge to coagulate for 8 minutes. The whole blood clot that is formed is then transferred to a non-adherent dressing and applied to the patient's wound. All FastSkin Patch kit elements and reagents are disposed of after a single use of the kit. The procedure may be repeated with a new FastSkin Patch kit after a few days.	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 and kaolin powder, 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.
Size of Final Blood Clot	Square: 5cmx5cm Area: 25cm^2	Diameter: 6cm diameter Area: 28.3 cm^2
Kit sterilization	Non sterile kit assembly with sterile components	Non sterile kit assembly with sterile components
Shelf Life	24 Months	24 Months

MimiX Biotherapeutics has demonstrated that the difference in technological characteristics of the subject device and the predicate device do not raise questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non Clinical:
The FastSkin Patch components were subjected to in vitro testing, with results demonstrating the device is safe for its intended use.

The FastSkin Patch coagulation cartridge was subjected to the following tests in its final sterile, packaged configuration:

- Performance validation
- Physico-chemical validation
- Sterility validation
- Bioburden validation
- Chemical cleanliness testing
- Shelf life validation
- Transit testing simulation validation
- Biocompatibility testing per ISO 10993-1

The FastSkin Patch coagulation initiator (kaolin) was subjected to the following tests in its final sterile, packaged configuration:

- Performance validation
- Physico-chemical validation
- Sterility validation
- Bioburden validation
- Shelf life validation
- Transit testing simulation validation
- Biocompatibility testing per ISO 10993-1

In accordance with the FDA guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing included:

- Chemical characterization
- Cytotoxicity Study
- Guinea Pig Maximization Sensitization Test
- Acute systemic toxicity
- Intracutaneous Study
- Acute Systemic Toxicity Study
- Pyrogen study
- Endotoxin study

The FastSkin Patch was also subjected to physico-chemical testing, identical to the physico-chemical testing performed on the predicate device to compare the outputs of the two devices. The results demonstrated that the whole blood clot output of FastSkin Patch is substantially equivalent to that of the predicate.

- Cell recovery
- Rheology
- Moisture content

In addition, bench testing was performed on the final FastSkin Patch to confirm that it functioned per its specifications throughout its shelf life. The device functioned as intended and all results passed, and considered equivalent to the performance of the predicate device.

Clinical:
The FastSkin Patch has been assessed in patients with diabetic foot ulcers. A summary from a multi-center, open label controlled clinical study comparing safety and efficacy of the FastSkin Patch to standard of care (SOC) in patients with chronic diabetic foot ulcers (DFUs) was provided as part of the submission. The study enrolled patients with DFU's between 1cm^2 and 25cm^2 in size, a history of at least 4 weeks chronicity and documented failure of prior treatments. Twenty patients completed treatment to 12 weeks or wound closure per the protocol (10 in treatment group and 10 in the control group with SOC alone). The Per Protocol analysis of the study showed that at Week 12 the incidence of complete wound closure was 60% (6 wound closures out of 10 patients) in the FastSkin Patch treatment group compared to 10% (1 wound closure out of 10 patients) in the control group. The FastSkin Patch was well tolerated with no treatment related adverse events.

Conclusions:
The FastSkin Patch has the same intended use, incorporates the same fundamental technology and has the same indications for use as the predicate. Based on the comparison of intended use and technological characteristics, MimiX Biotherapeutics has demonstrated that the FastSkin Patch is substantially equivalent to the predicate device and is safe and effective for its intended use.