510(K) SUMMARY

1. SUBMITTER

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2. DEVICE

Name of Device:	3C Patch System Model Number 5503
Common or Usual Name:	Peripheral blood processing device for wound management
Classification Name:	21 CFR 864.9245- Automated blood cell separator
Regulatory Class:	II
Product Code:	PMQ

3. PREDICATE AND REFERENCE DEVICES

Predicate Device Name:	3C Patch System (BK170002)
Manufacturer:	Reapplix A/S
510(k) Number:	BK170002
Reference Devices:	RD2 System
Manufacturer:	RedDress ltd.

510(k) Number: BK190349

Purpose: Supports labeling changes

4. DEVICE DESCRIPTION

The 3C Patch System uses a 2-step mechanical centrifugation process, requiring no reagent additives, to produce an autologous platelet-rich plasma (PRP) gel for direct application to cutaneous wounds.

The primary components of the 3C Patch System, as a whole, include:

(1) 3C Patch Kit;

(2) 3C Patch Counterbalance

(3) 3C Patch Centrifuge

The key components of the cleared 3C Patch System that are in the blood path include the legally marketed sterile venipuncture needle set and the 3C Patch Device. The 3C Patch Device and 3C Patch Needle Holder are constructed of medical grade polyester (PET) and are sterilized by Reapplix using gamma radiation. The other components/materials with blood contact are the brombutyl rubber plug and natural butyl rubber O-ring.

5. INDICATION FOR USE

The 3C Patch® 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 peripheral blood. Under the supervision of a healthcare professional, the PRP gel produced by the 3C Patch® System 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.

The indication of the current device is the same as the predicate. There are no changes to the indications for use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Technological features, material, design and performance of the device remain unchanged. The following is a tabular comparison of the devices.

Device Comparison Table:1

	Subject Device	**Predicate Device (BK170002)**
Applicant	Reapplix Aps	Reapplix Aps

	Subject Device	Predicate Device (BK170002)
Trade Name	3C Patch System	3C Patch System
Classification Regulation	21 CFR 864.9245	21 CFR 864.9245
Product Code	PMQ	PMQ
Indications for Use	The 3C Patch 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 peripheral blood. Under the supervision of a healthcare professional, the PRP gel produced by the 3C Patch System 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.	Same
3C Patch Kit	This kit includes the sterile 3C Patch Device and 3C Patch Needle Holder. These components are constructed of medical grade polyester (PET) and are sterilized by Reapplix A/S using gamma radiation. − In addition, this kit includes accessory components to draw blood (venipuncture needle set, skin preparation alcohol swab, and post-sampling adhesive bandage) and to cover the 3C Patch wound gel patch. These accessories are existing legally marketed products for blood access and wound management.	Same
3C Patch Centrifuge Insert Kit	This kit includes the 3C Patch Holder with Holder Inserts, Inner Spring and Inner Plate, and the 3C Patch Outer Spring.	Same

	Subject Device	**Predicate Device (BK170002)**
3C Patch Centrifuge	The users have the option of 2 centrifuges as part of the 3C Patch System: the third-party commercially available Eppendorf 5702 centrifuge, which was cleared for use with the 3C Patch System under BK140211; or the 3C Patch Centrifuge.	Same
3C Patch Counterbalance	The 3CP™ Counterbalance is a non-sterile centrifuge accessory component. It is used to counterbalance the 3C Patch® Device	Same
	when an odd number of devices (1 or 3) are used.	
Contraindication Revision	Do not use PRP gel from the 3C Patch System on: - Actively infected wounds - Malignant wounds - Patients with sepsis or bacteraemia - **Patients with large wounds, active systemic disorders, and abnormal laboratory tests, such as the following:** o **Wounds greater than 10cm^2**	Do not use PRP gel from the 3C Patch System on: - Actively infected wounds - Malignant wounds - Patients with sepsis or bacteraemia - **Patients with a monthly blood draw of more than 250 ml**

	o **Coronary artery disease, congestive heart failure, liver failure, and renal failure on hemodialysis, and active gastrointestinal bleeding** o **Hemoglobin less than 10g/dl, platelet count less than100x10^9/L, and serum albumin level less than 2.5g/dl**	

The modification to the contraindications clarifies the primary underlying reason for contraindicating the use of the device in these patient groups, which is the volume of blood drawn. The modified contraindications are consistent with other devices for the same intended use, such as the RD2 System (CK190349). The indications for use and technical characteristics of the subject and predicate device are identical. In conclusion, the differences in labeling do not raise new questions of safety and effectiveness.

7. PERFORMANCE DATA

Performance data was not required to support the labeling changes that were included as part of this submission.

8. CONCLUSIONS

Based on the identical indications for use, technological characteristics, material, design, engineering, operating principle, and performance claims the 3C Patch with the revised contraindication and warnings can be concluded to be substantially equivalent to the cleared and currently marketed predicate device 3C Patch BK170002.