In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the 3C Patch System is provided below.

1. SUBMITTER

Reapplix ApS
Blokken 45
3460 Birkerød
Denmark

Contact Person: Niels Erik Holm, Chief Operating Officer, Reapplix ApS
Phone: 011 45 2622 1962
Fax: 011 45 7014 1685
neh@reapplix.com

Date Prepared: March 28, 2017

2. DEVICE

Name of Device: 3C Patch System
Common Name: Peripheral blood processing device for wound management
Classification Regulation: 21 CFR 864.9245
Regulatory Class: II
Product Code: PMQ
Panel: Hematology

3. PREDICATE DEVICE

Predicate: 3C Patch System (BK140211)

4. DEVICE DESCRIPTION

With this 510(k), the device description was expanded to include the following new components to the 3C Patch System: (1) 3C Patch Centrifuge with power supply and (2) 3C Patch Counterbalance (minor modifications in dimensions).

The 3C Patch System is a single use medical device used to prepare an autologous platelet-rich plasma (PRP) gel from the patient's peripheral blood by centrifugation, without the addition of any reagents.

As a whole, the 3C Patch System consists of:

- 3C Patch Kit
  - This kit includes the sterile 3C Patch Device and 3C Patch Needle Holder.
  - 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.

- 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.
- 3C Patch Counterbalance
- 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 new 3C Patch Centrifuge.

The 3C Patch System uses a mechanical centrifugation process, requiring no reagent additives, to produce an autologous PRP gel for direct application to cutaneous wounds as specified in the Indications for Use, below.

The key components of the 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 ApS using gamma radiation. The other components/materials with blood contact are the brombutyl rubber plug and natural butyl rubber O-ring.

5. INDICATIONS FOR USE

The indications for use for the 3C Patch System remain the same as that cleared under BK140211:

> 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The similarities and differences in technological characteristics between the subject 3C Patch System and the predicate 3C Patch System of BK140211 are summarized below.

6.1. Similarities

At a system level:

- There is no change to the 3C Patch Kit.
- There is no change to the 3C Patch Centrifuge Insert Kit.

- The Eppendorf 5702 Centrifuge remains as option for users.
- The 3C Patch System will continue to use only the patient's own peripheral blood (i.e., no reagents) to create the PRP gel.

At a centrifuge level:

- Both the 3C Patch Centrifuge and the Eppendorf 5702 Centrifuge have comparable power requirements, rpm, g-forces, permissible density of material being centrifuged, noise, ambient temperature, and maximum relative air humidity.
- The physico-chemical attributes between the 3C Patch produced by the 3C Patch Centrifuge and the Eppendorf 5702 Centrifuge are substantially equivalent.

6.2. Differences

At a system level:

- A second centrifuge (i.e., 3C Patch Centrifuge) was added to the system as an option for users.
- The 3C Patch Counterbalance was slightly modified in dimensions.

At a centrifuge level:

- The 3C Patch Centrifuge has optical sensors that detect coagulation by measuring the light transmission through the 3C Patch Device. The transmission will decrease as the fibrin is polymerized. Evidence that this technology works is shown by the software testing and the PRP output testing.

7. PERFORMANCE DATA

Software, EMC, electrical, and bench (PRP output) testing was performed to support the substantial equivalence of the modified 3C Patch System to the 3C Patch System cleared under BK140211. Clinical data were not required to support substantial equivalence.

7.1. Physico-chemical Testing of the 3C Patch

PRP gels were produced using the 3C Patch Centrifuge and Eppendorf 5702 Centrifuge. The following physico-chemical parameters were tested:

- Moisture content (%)
- Cell Recoveries (%) - Platelets
- Cell Recoveries (%) – White Blood Cells
- Cell Recoveries (%) – Red Blood Cells
- Clot strength, measured by the maximal break force
- Shear strength, measured by the percent elongation before first tear
- Gel stiffness, determined by the force needed to stretch the PRP gel (N/mm)

The physico-chemical test parameters of moisture content, platelet recoveries, WBC recoveries, clot strength, shear strength, and gel stiffness met the predefined study acceptance criterion of a 20% difference (0.8, 1.25) between 3C Patches produced by the 3C Patch Centrifuge versus the Eppendorf 5702 Centrifuge. Furthermore, all of these test parameters met the reproducibility acceptance criterion of ≤20%.

The physico-chemical test parameter of RBC recovery met the predefined <5% acceptance criteria for the 3C Patches produced by both the 3C Patch Centrifuge and Eppendorf 5702 Centrifuge.

Therefore, the substantial equivalence of the 3C Patch Centrifuge-derived patch to the predicate Eppendorf 5702 Centrifuge-derived patch has been demonstrated.

7.2. Software

With the modification of the 3C Patch System to include a new centrifuge (i.e., 3C Patch Centrifuge), Reapplix provided software information consistent with FDA's software guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Documentation was provided consistent with a "Minor" Level of Concern.

7.3. EMC and Electrical Safety

EMC testing of the 3C Patch Centrifuge was performed in accordance with EN/IEC 61326-1:2013. All tests passed.

Electrical safety testing of the 3C Patch Centrifuge was performed in accordance with EN/IEC 61010-1:2001, 2nd edition and EN/IEC 61010-2-20:2006. All tests passed. A rationale as to why the testing conducted as per the second edition of EN/IEC 61010-1 demonstrates conformance to the third edition of EN/IEC 61010-1 (61010-1:2010).

Testing demonstrating compliance of the power supply to EN/IEC 60950-1:2005 + A1 (2009) + A2 (2013) was also provided.