

**510(k) Submission For
3C OrthoPatch Device
Reapplix A/S**

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

510(k) Number: BK230968

1. Administrative Information

Submitter: Reapplix A/S
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2. Date prepared: March 29, 2024

3. Purpose of Submission: New Device to obtain a substantial equivalence for the 3C OrthoPatch Device

4. Type of Device: Traditional

5. Proprietary and Established Names:
3C OrthoPatch Device

6. Regulatory Information:

Regulation section: 864.9245 - Automated blood cell separator
Classification: Class II
Product Code: ORG
Panel: Hematology

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7. Indication for Use:

The 3C OrthoPatch Device is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) from a small sample of a patient's own peripheral blood. The PRP produced by the 3C OrthoPatch Device is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

8. Device Description:

The 3C OrthoPatch Device uses mechanical centrifugations process, requiring no reagent additives, to produce an autologous platelet-rich plasma (PRP) gel, which is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. The 3C OrthoPatch Device is intended to be used at point-of-care for the safe and rapid preparation of PRP gel from a small sample of a patient's own peripheral blood under the supervision of a healthcare professional.

The 3C OrthoPatch Device is able to draw blood by vacuum and then separate the blood components by centrifugation to create a platelet-rich plasma (PRP) gel consisting of fibrin, platelets and leukocytes.

The 3C OrthoPatch Device and 3C Patch Needle Holder are constructed of medical grade polyester (PET) and polypropylene (PP) and are sterilized using gamma radiation.

9. Substantial Equivalence Information:

Predicate device name(s): Intra-Spin System

Predicate K number(s): K120048

Comparison with predicate:

Technology: Both the predicate device and the 3C OrthoPatch Device include centrifugation to separate red cells and plasma fractions to form a PRP gel. The 3C OrthoPatch Device use centrifugation to compact the gel into a flat gel patch whereas Intra-Spin System is manually compacted into a flat gel patch.

	Subject Device	Predicate Device	Substantial Equivalence Comparison
510(k) Number	BK230968	K120048	
Applicant	Reapplix A/S	Intra-Lock International	

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	Subject Device	Predicate Device	Substantial Equivalence Comparison
Trade Name	3C OrthoPatch Device	Intra-Spin System	
Classification Regulation	21 CFR 864.9245	21 CFR 864.9245	Same
Product Code	ORG	ORG	Same
Indications for Use	The 3C OrthoPatch Device is intended to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) from a small sample of a patient's own peripheral blood. The PRP produced by the 3C OrthoPatch Device is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The Intra-Spin System is intended to be used for the safe and rapid preparation of autologous platelet rich fibrin (PRF) from a small sample of blood at the patient's point of care. The PRF is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	Same
Device Kit	This kit includes the sterile 3C OrthoPatch Device and 3C Patch Needle Holder. These components are constructed of medical grade polyester (PET) and (PP). They are sterilized by Reaplix A/S using gamma radiation. Accessory components are included for draw blood.	Greiner Bio-One Tube 9ml Serum Clot activator, red cap (single use) Greiner Safety Blood Collection Set + Holder, 21G (single use) Latex Free Tourniquet Test Tube Rack	Similar The material safety of each component of the subject device has been ensured and meets the requirements in previous submission.

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	Subject Device	Predicate Device	Substantial Equivalence Comparison
Instrument needed for process	3C Patch centrifuge with external power supply, power cable, contra weight, hex hand wrench, tools for rotor change.	IntraSpin Centrifuge Power Cable Fuse Hex Hand Wrench	Similar
Accessory	The 3CPTM Counterbalance is a non-sterile centrifuge accessory component. It is used to counterbalance the 3C OrthoPatch Device when an odd number of devices (1 or 3) are used.	Greiner Bio-One balancing tubes White Cap 9ml	Similar
Usage	Single use only	Single use only	Same
Sterile	Yes, using gamma irradiation	Yes, using gamma irradiation	Same

Standard/Guidance Document referenced (if applicable):

Not Applicable. The submission does not utilize voluntary consensus standards.

10. Summary of Performance Data Supporting the Substantial Equivalence

Non-Clinical Tests:

A series of non-clinical safety and performance studies were conducted on the subject device.

- Biocompatibility
- Sterilization verification
- Shelf life
- Performance testing included are:
 - Bone Material Cohesion
 - Platelet Recovery
 - WBC Recovery
 - RBC Recovery
 - pH

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All test results meet the pre-defined acceptance criteria and meet intended use.

Clinical Tests:

No clinical testing was performed. Clinical data and conclusions were deemed not necessary to establish substantial equivalence between the subject device and predicate device.

11. Propose Labeling:

The labeling is sufficient, and it satisfies the requirements of 21 CFR Part 809.10.

12. Conclusion:

The submitted information in this premarket notification supports a substantial equivalence decision.