BK190393 email supplement

Section 5 - 510(k) Summary (revised)

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 06/04/2020

5.3 Submitter: Aeon Biotherapeutics Corp.

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5.4 Identification of the Device:

Proprietary/Trade name:	Aeon CPKit
Classification Product Code:	ORG
Regulation Number:	864.9245
Regulation Description:	Automated blood cell separator.
Review Panel:	Hematology
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	RegenKit-BCT Family Kits
Manufacturer:	RegenLab SA
Classification Product Code:	ORG
Regulation number:	864.9245
Device Class:	II
510(k) Number:	BK110061

5.6 Indications for Use / Intended Use of the Device

The Aeon CPKit is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.

5.7 Description of the Device

The device is used for preparation of autologous platelet-rich plasma (PRP).

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, Aeon CPKit.

- Sterilization verification
- Shelf life
- Biocompatibility
- Performance testing

All the test results demonstrate that Aeon CPKit meets the requirements of its pre-defined acceptance criteria and intended use.

5.9 Clinical and Usability Testing

No clinical data was used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The Aeon CPKit submitted in this 510(k) file is substantially equivalent in intended use, technology/mechanism of action, safety and performance to the cleared device, RegenKit-BCT Family Kits (BK110061). Differences between the devices are cited as below.

Item	Subject device	Predicate device	Substantial Equivalence Discussion
Manufacturer	Aeon Biotherapeutics Corp.	RegenLab SA	
Trade Name	Aeon CPKit	RegenKit-BCT Family Kits	
510(k) No.	BK190393	BK110061	
Indications For Use	The Aeon CPKit is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.	The RegenKit®-BCT Family Kit is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	***Same***
System Components	Tube set	Butterfly needle, Collection holder, Tube, Transfer device, Transfer needle, Syringe	***Equivalent*** The subject device does not include higher risk accessories like needle. This difference does not raise any new issue of substantial equivalence.
Mechanism of Action	Separation based on blood density	Separation based on blood density	***Same***
Method of Processing	Centrifugation	Centrifugation	***Same***
Usage	For single use only	For single use only	***Same***
Sterile	Yes	Yes	***Same***

5.11 Similarity and Difference

The Aeon CPKit is compared with *RegenKit-BCT Family Kits*. The subject device has same intended use and technology/mechanism of action, and similar safety and performance characteristics as the predicate device. Although there are some different specifications between these devices, the performance test was completed and demonstrated similar test results. The subject device has also undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device and the predicate device do not raise any new issue of substantial equivalence.

5.12 Conclusion

After analyzing non-clinical laboratory studies, safety and performance testing data, it can be concluded that the Aeon CPKit is substantially equivalent to the predicate device in intended use, design and performance claims.