# 510(k) SUMMARY

**5.1 Type of Submission:** Traditional

**5.2 Date of Summary:** 01/05/2024

**5.3 Submitter:** Aeon Biotherapeutics Corp.


**Address:** 6F., No. 866-3, Zhongzheng Rd., Zhonghe Dist., New Taipei City 23586, Taiwan (R.O.C.)
**Phone:** (b) (6)
**Contact:** Willy Wang
(qa@theaeon.com.tw)


**5.4 Identification of the Device:**

| | |
|---|---|
| **Proprietary/Trade name:** | Aeon ACKit |
| **Classification Product Code:** | ORG |
| **Regulation Number:** | 864.9245 |
| **Regulation Description:** | Platelet And Plasma Separator For Bone Graft Handling |
| **Review Panel:** | Hematology |
| **Device Class:** | II |

**5.5 Identification of the Predicate Device:**

| | |
|---|---|
| **Predicate Device Name:** | Aeon CPKit |
| **Applicant:** | Aeon Biotherapeutics Corp. |
| **Classification Product Code:** | ORG |
| **Regulation number:** | 864.9245 |
| **Device Class:** | II |
| **510(k) Number:** | BK190393 |

## 5.6 Indications for Use / Intended Use of the Device

The Aeon ACKit 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 non-clinical safety and performance studies were conducted on the subject device, Aeon ACKit.

- Sterilization verification
- Shelf life
- Biocompatibility
- Performance testing
  - Functional test
  - Blood cell integrity
  - Platelet p-selecting expression
  - Platelet aggregation ability
  - pH value
  - Hypotonic Shock Response (HSR)
  - Bone graft cohesion

All test results demonstrated that subject device meets the requirements of its pre-defined acceptance criteria and intended use.

## 5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence. The safety and effectiveness of finished Aeon ACKit have been established through previous non-clinical performance testing.

## 5.10 Substantial Equivalence Determination

The Aeon ACKit submitted in this 510(k) file is substantially equivalent in indications for use/intended use, technology/mechanism of action, and safety and performance claims to the cleared device, Aeon CPKit (BK190393). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

| Item | Subject Device | Predicate Device | Substantial Equivalence Discussion |
|---|---|---|---|
| Manufacturer | Aeon Biotherapeutics Corp. | Aeon Biotherapeutics Corp. | |
| Trade Name | Aeon ACKit | Aeon CPKit | |
| 510(k) No. | BK231016 | BK190393 | |
| Indications for Use / Intended Use | The Aeon ACKit 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 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. | ***Same*** |
| System Components | Tube set | Tube set | ***Same*** |
| Mechanism of Action | Separation based on blood density | Separation based on blood density | ***Same*** |
| Mode of Processing | Centrifugation under force 1500G, 8 min. | Centrifugation under force 1650G, 8 min. | ***Similar***<br>The centrifugation values of the subject device have been validated and meet the requirements. Thus, the equivalence would not be affected. |
| Usage | For single use only | For single use only | ***Same*** |

| | | | | |
|---|---|---|---|---|
| Sterile | | Yes, using Gamma Irradiation Sterilization ($VD_{max}^{25}$) | Yes, using Gamma Irradiation Sterilization ($VD_{max}^{25}$) | ***Same*** |
| Component | | Tube, stopper, separation gel, Sodium citrate, blister and Tyvek | Tube, stopper, separation gel, blister and Tyvek | ***Similar***<br>The material safety of each component of the subject device has been ensured and meets the requirements. Besides, each performance has been validated through the performance tests of the subject device. Thus, the equivalence would not be affected. |
| Specification | Sterile Barrier | Single layer and double layer blister | Single layer and double layer blister | ***Same*** |
| | Capacity | 9 ml ~ 27 ml | 5 ml ~ 10 ml | ***Similar***<br>The performances of the subject device are not affected and meet the requirements. Thus, the equivalence would not be affected. |
| | Package | Single blister and double blister | Single blister and double blister | ***Same*** |

## 5.11 Similarity and Difference

The Aeon ACKit is compared with *Aeon CPKit*. The subject device has same indications for use/intended use and technology/mechanism of action, and similar safety and performance as the predicate device.

In section 5.10 Substantial Equivalence Determination, several items are justified as similar. A comprehensive overview of these items is provided as follows:

- Component

  The material of the tube, separation gel and sodium citrate are different between the subject and predicate device. All of these material safeties have been ensured by corresponding CoA/SDS/Test report. Besides, the biocompatibility and performance of the finished subject device were validated. The subject device is found to safely function with respect to its intended use, and the material is reliable.

  For the blister used in the subject and predicate device, the materials, sealing width and sealing conditions are the same. The performance of the blister has been validated through packaging system test. The test result of the blister demonstrates that it can effectively serve as the barrier to maintain the safety of the subject device.

- Centrifugation value

  The centrifugation value of the subject device and the predicate device is 1500G/8min. and 1650G/8min. respectively. The centrifugation values for the subject device have been validated through the functional test report, and the test results shows that the subject device can effectively prepare the PRP with respect to its intended use.

- Specification

  The capacity is different between the subject and predicate device. This specification would not affect the performances of the subject device and meet the requirements.

Nevertheless, safety and performance tests were conducted on the subject device, and all the tests were verified to meet the required acceptance criteria. The result of the safety and performance tests indicated that aforementioned differences do not affect the indications for use/intended use of the subject device or raise any unresolved issues.

Therefore, any differences between the subject device and the predicate device are insignificant, and do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, design and performance claims.

## 5.12 Conclusion

After analyzing non-clinical laboratory studies, safety and performance testing data, it can be concluded that the Aeon ACKit is substantially equivalent to the predicate device.