Section V

Summary

HEALEON MEDICAL
THE REGENERATIVE RESOURCE

510(k) Summary
Prepared: January 24, 2020

I.	**Company**	Healeon Medical, Inc. 1090 Lawrence Dr., Suite 101 Newbury Park, CA 91320
II.	**Contact**	Trevor J. Denbo Regulatory Submissions 949-424-7607 Regulatory@healeonmedical.com
III.	**Product Trade Name**	Healeon Duet
IV.	**Common Name**	Platelet and Plasma Separator for Bone Graft Handling
V.	**Classification Name**	Automated blood cell separator
VI.	**Regulation Number**	21 CFR 864.9245
VII.	**Device Class**	Class II
VIII.	**Classification Product Code**	ORG
IX.	**Predicate Device**	BK190406 Arthrex Double Syringe (ACP)® System

X. Description

The Healeon Duet tube is a sterile, single use, syringe assembly that is intended for separating and concentrating blood components along with the use of a desktop centrifuge. It enables blood to be separated and aspirated in a single device after centrifugation.

The Healeon Duet consists of a syringe with a hollow threaded plunger that provides a secondary chamber and locking collar that engages the thread plunger for the controlled collection of whole blood and the separation of platelet rich plasma. A sample is introduced to the main chamber of the syringe, the locking collar is engaged, and centrifugation is performed. The whole blood is separated into discrete gradient layers based upon density with the plasma located on top and the buffy coat suspended directly below followed by the red blood cells at the distal end of the syringe. The secondary chamber located inside the plunger is opened through a control valve and with a twisting motion downward the upper plasma layer securely enters the secondary chamber until the buffy coat is captured. Once the plasma and buffy coat are secured the secondary chamber is closed and the red blood cells and residual hematocrit are dispelled out of the syringe.

The threaded plunger with its secondary hollow chamber enables controlled capture of the plasma for forms a stable barrier between the plasma layers and the hematocrit components.

The centrifuge and blood draw accessories are not included with the system and is not a part of the present submission.

XI. Indications for Use

Healeon Duet is indicated 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 point-of-care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

XII. Summary of the Technological Characteristics

The Healeon Duet is an improved syringe assembly, intended for the collection of whole blood and the separation of platelet rich plasma in a single device after they have been centrifuged. The Healeon Duet consists of a syringe with a hollow threaded plunger that provides a secondary chamber and locking collar that engages the thread plunger for the controlled collection of whole blood and the separation of platelet rich plasma

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation of the subject device are substantially equivalent to the predicate device. All devices are provided as sterile concentrating systems, designed to concentrate and aid in separation of a starting source material (blood) by density using a centrifuge. All devices include a single-use, disposable receptacle (e.g. concentrating device, separator, centrifuge tube assembly, etc.) that is designed to accept a volume of blood, and then undergo centrifugal processing in order to obtain platelet rich plasma (PRP). The table below summarizes the comparison of characteristics between the subject and predicate devices.

	Arthrex Double Syringe (ACP) (BK190406)	**Healeon Duet (Subject Device)**
Indications for Use	The Arthrex Double Syringe (ACP) Kit is indicated 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 for improving handling characteristics.	Healeon Duet is indicated 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 point-of-care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
Regulation	21 CFR 864.9245	Identical
Device Class	II	Identical
Device Code	ORG	Identical
System Components	• Upper syringe • Lower syringe • Threaded cap	• Syringe assembly • Threaded cap
Materials	Polypropylene, Thermoplastic elastomer, Silicone, ACD-A	(b) (4) Thermoplastic elastomer, (b) (4)
Principle of Operation	Separation of blood based on density	Identical
Energy source	Manual	Identical
Method of Processing	Centrifugation	Identical
Centrifuge Device	General purpose centrifuge	Identical
Sterile	Yes	Yes
Sizes	15 mL	25mL

XIII. Discussion of the Non-Clinical Testing

Biocompatibility Testing

Biocompatibility testing on the patient contacting materials of the device was conducted in accordance with ISO 10993-1 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. Per ISO 10993-1, the Healeon Duet is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with indirect blood contact. Testing included cytotoxicity (per ISO 10993-5), sensitization & intracutaneous reactivity (per ISO 10993-10), acute systemic toxicity (per ISO 10993-11), pyrogenicity per USP: 151 and USP 41-NF 36 .

Sterilization Validation

A sterilization dose qualification using the half-cycle method in compliance with ISO 11135:2014 was performed to validate an ethylene oxide sterilization process for the Healeon Duet. Results demonstrated that the product is reliably sterilized to a 10^{-6} sterility assurance level (SAL) using these predetermined parameters. Healeon intends to use this same procedure to increase sterilization efficiency, such as load capacity, configuration, or location post clearance.

Transport and Shelf-life

A transportation validation per ASTM D4169 and a packaging shelf life validation per ISO 11607 was conducted using accelerated aging to demonstrate that the package is designed, manufactured, and packed in such a way that the characteristics and performances of the packaging during the intended use will not adversely be affected during the full life cycle of the device; that there is assurance that the device is sterile when placed in the market and will remain sterile, under the storage and transport conditions laid down, until the protective packaging is opened; and that the product will be kept without deterioration at the high level of cleanliness so as to minimize the risk of microbial contamination.

Usability / Human Factors

A validation was conducted to demonstrate that the Healeon Duet user interface was designed and engineered to maximize the likelihood that this product will be safe and effective for the intended users, uses, and use environments.

Predicate Equivalency Evaluation

A study was conducted to compare platelet concentrates produced by the Healeon Duet and those produced by the predicate. Parameters included platelet yields, platelet recoveries, average PRP platelet concentration, pH, p-selectin expression on resting platelets, platelet response to ADP-stimulation, platelet function, platelet aggregation, hypotonic stress response, and Bone graft material retention. This evaluation demonstrated that the platelet concentrates obtained by the Helean Duet is substantially equivalent to those of the predicate.

Additionally, the Healeon Duet and the predicate possess the same indications, device class, device code, principles of operation, methods of processing, sterility assurance level, and biocompatibility. The subject device uses components readily available to the user, and the size, where the larger size of the subject device provides increased usability. None of the differences negatively impact the device's substantial equivalence when compared to the predicate. All validations, verifications, and qualifications passed the predetermined acceptance criteria. The Healeon Duet therefore has been shown to be substantially equivalent to the predicate.

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