BK241095
510(k) Summary

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III.	**Product Trade Name**	Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45)
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**	BK170136, Healeon PRP Platelet Preparation System

X. Description

The Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) consists of an evacuated tube intended for the collection of whole blood and the separation of platelet rich plasma. The plasma separator component is comprised of a biocompatible polymer blend of precise mass and configuration that is free to float while under centrifugal force but is sealed in place under normal conditions. This configuration permits a convenient means of plasma separation and provides a reliable method for retaining platelet rich plasma without the risk of remixing the blood components.

This device is a sterile, single use, vacuum evacuated tube that is intended for separating and concentrating blood components along with the use of a desktop centrifuge. The tube contains the separator component, an anticoagulant, and a stopper at the top.

The centrifuge is not included with the device and is not a part of the present submission.

XI. Indications for Use

The Healeon Float PRP devices (HFPRP15, HFPRP30 and HFPRP45) are intended for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of 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 Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) is a separator component and anticoagulant within a stoppered evacuated tube. It is intended for the collection of whole blood and for the safe and rapid preparation of autologous platelet rich plasma (PRP). The plasma separator is comprised of a biocompatible polymer blend of precise mass and configuration that is free to float while under centrifugal force but is locked in place when the centrifuge stops. This configuration drastically limits the potential for remixing of blood components.

The fundamental scientific technology, materials of construction, processing methods and mechanism of operation are similar between the subject and predicate devices. All devices are provided sterile and are designed to concentrate and aid in separation of a starting source material (blood) by density through the use of a centrifuge. All devices are made of medical grade polymers and elastomers suitable for use in medical devices, the predicate also includes (b) (4) gel. All devices include a single-use, disposable receptacle (i.e. concentrating device with separator) that is designed to accept a volume of blood, and then undergo centrifugal processing to obtain platelet concentrate (PRP). The table below summarizes the comparison of technological characteristics between the subject and predicate devices.

	Predicate Device (BK170136, Healeon HD PRP)	**Subject Device** (Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45))
Indications for Use	The Healeon HD PRP 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 point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The Healeon Float PRP devices (HFPRP15, HFPRP30 and HFPRP45) are intended for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of 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.
Components	• PRP Tube • Stopper • Separator component, gel • ACD-A Anticoagulant	• PRP Tube • Stopper • Separator component, float • ACD-A Anticoagulant
Materials	• Tube and Stopper: medical grade polymers and elastomers	• Tube and Stopper: medical grade polymers and elastomers • Separator Component: Polymer blend.

	• Separator Component: (b) (4) Gel • Anticoagulant: Acid Citrate Dextrose	• Anticoagulant: Acid Citrate Dextrose
Principle of Operation	Separation of blood based on density	Same as predicate
Method of Processing	Centrifugation	Same as predicate
Centrifuge Device	General purpose centrifuge	Same as predicate
Sterile	Yes	Same as predicate
Sizes	15mL and 30mL	15mL, 30mL, 45mL

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 device is categorized as an externally communicating device, with limited exposure (contact < 24 hours) with blood path, indirect contact. Testing included cytotoxicity (per ISO 10993-5), skin sensitization (per ISO 10993-10), irritation (per ISO 10993-23), acute systemic toxicity, pyrogenicity (per ISO 10993-11), and hemocompatibility (per ISO 10993-4).

Sterilization Validation

A sterilization qualification using the (b) (4) method in compliance with (b) (4) was performed to validate a (b) (4) sterilization process for the Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45). Results demonstrated that the product is reliably sterilized to a (b) (4) sterility assurance level (SAL) using predetermined parameters. Bimini Health Tech intends to use this same procedure to increase sterilization efficiency, such as load capacity, configuration, or location post clearance.

Shelf-life and Transport

A transportation validation per ASTM D4169 and a packaging shelf-life validation per ISO 11607 was conducted using 2 year 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. To this end, this testing provided assurance that the device is sterile when placed in the market and will remain sterile, under the established storage and transport conditions, until the protective packaging is opened. This testing further demonstrates that the product will be kept without deterioration at the high level of cleanliness to minimize the risk of microbial contamination. Bimini Health Tech intends to use this same procedure to increase the product shelf life. The shelf-life claimed for the devices is one year.

Predicate Equivalency Evaluation

A study was conducted to compare platelet concentrates produced by the Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) and those produced by the predicate. Parameters included acceptable platelet yield, platelet concentration, CBC values, pH, platelet activation, platelet aggregation, hypotonic stress response, and bone graft handling

characteristics. This evaluation demonstrated that the platelet concentrates obtained by the Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) is substantially equivalent to those of the predicate.

Additionally, the Healeon Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) and the predicate possess the same indications, device class, device code, principles of operation, methods of processing, sterility assurance level, and equally biocompatibility for its purpose. The subject device offers a larger size to provide 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 Float PRP devices (HFPRP15, HFPRP30, and HFPRP45) therefore has been shown to be substantially equivalent to the predicate.