BK251248
510(k) Summary

I.	**Company**	Bahia Medical, Inc. 7250 Dallas Parkway Suite 400 Plano, TX 75024 United States
II.	**Contact**	Luis Mendoza Director, Operations (b) (6)
III.	**Product Trade Name**	*PRiSM PRP*
IV.	**Common Name**	Platelet and Plasma Separator for Bone Graft Handling
V.	**Classification Name**	Platelet And Plasma Separator For Bone Graft Handling
VI.	**Regulation Number**	21 CFR 864.9245
VII.	**Device Class**	Class II
VIII.	**Classification Product Code**	ORG
IX.	**Predicate Device**	BK170096 Cascade Medical FIBRINET® System (Selphyl)

X. Description

PRiSM PRP consists of an evacuated tube intended for the collection of whole blood and the separation of platelet rich plasma. The plasma separation medium is comprised of a (b) (4) gel that moves 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

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

PRiSM PRP consists of a separator component and anticoagulant within a stoppered evacuated tube. It is intended for the collection of whole blood and the of platelet rich plasma. The plasma separation medium is comprised of a (b) (4) gel that moves while under centrifugal force but is sealed 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.

	Subject Device (PRiSM PRP)	**Predicate Device** (BK170096)
Indications for Use	The PRiSM 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 Cascade Medical FIBRINET® System 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.
Components	• PRP Tube • Stopper • Separator component, gel • ACD-A Anticoagulant	• PRP Tube • Stopper • Separator component, gel • Butterfly needle • Syringes • Sterile needles • Vacutainer tube holder • Connector • Needle
Materials	• Tube and Stopper: medical grade polymers and elastomers • Separator Component: (b) (4) Gel	• Tube and Stopper: medical grade polymers and elastomers

	• Anticoagulant: Acid Citrate Dextrose	• Separator Component: (b) (4) Gel Anticoagulant: Sodium Citrate
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	10, 20, and 35 mL	9mL

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 indirect contact with blood. Testing included cytotoxicity (per ISO 10993-5), skin sensitization (per ISO 10993-10), irritation (per ISO 10993-23), acute systemic toxicity, in-vitro hemolytic, in-vitro complement activity, and pyrogenicity (per ISO 10993-11).

RPT-004-01_B Protocol, Biocompatibility Testing for Bahia PRP
RPT-004-02_B Report, Biocompatibility Testing for Bahia PRP

Sterilization Validation

A sterilization qualification using the (b) (4) method in compliance with ISO 11137 was performed to validate a (b) (4) sterilization process for the PRiSM PRP. Results demonstrated that the product is reliably sterilized to a 10^{-6} sterility assurance level (SAL) using predetermined parameters. Bahia Medical intends to use this same procedure to increase sterilization efficiency, such as load capacity, configuration, or location post clearance.

RPT-005-01_A Protocol, Sterilization Validation for PRiSM PRP and PRFM Tubes
RPT-005-02_A Report, Sterilization Validation for PRiSM PRP and PRFM Tubes

Transport, Shelf-life, and Transport

A transportation validation per ASTM D4169 and a packaging shelf-life validation per ISO 11607 was conducted using 1 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. Bahia Medical intends to use this same procedure to increase the product shelf life. The claimed product shelf life will be 6 months. Although the Package Integrity supports a 12 month shelf-life, the Product Integrity was only tested to support a 9 month shelf-life and the Biological Verification was performed on product that had a 6.7 month shelf-life. Given the potential variability in

terms of the exact day of the month that the sterilization can occur and the different days of months, it has been chosen to round down to a 6 month claimed product shelf life.

RPT-001-01_B Protocol, 1 Year Acc. Age PRiSM PRP and PRFM Package Integrity
RPT-001-02_B Report, 1 Year Acc. Age PRiSM PRP and PRFM Package Integrity
RPT-002-01_B Protocol, 6 mo. RT Age PRiSM PRP and PRFM Package Integrity
RPT-002-02_B Report, 6 mo. RT Age PRiSM PRP and PRFM Package Integrity
RPT-006-01_A Protocol, 9mo RT Age Bahia PRP Product Integrity
RPT-006-02_A Report, 9mo RT Age Bahia PRP Product Integrity

Predicate Equivalency Evaluation

A study was conducted to compare platelet concentrates produced by *PRiSM PRP* 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 PRiSM PRP is substantially equivalent to those of the predicate.

RPT-003-01_B Protocol, PRiSM PRP Biological Verification
RPT-003-02_B Report, PRiSM PRP Biological Verification

Additionally, *PRiSM PRP* and the predicate possess the same indications, device class, device code, principles of operation, methods of processing, sterility assurance level, and equivalent 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. *PRiSM PRP* therefore has been shown to be substantially equivalent to the predicate.