510(K) SUMMARY

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(b) (6)

(a)(2). Proprietary Name: RegenBMC®

Common Name(s) Platelet and plasma separator for bone graft handling

Classification Name: 21 CFR 864.9245 Automated blood cell separator

Regulatory Class: Class II

Product Code: ORG

(a)(3). Primary Predicate Device:

Primary Predicate: BK210655 – Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System

Reference Device: BK090048 - RegenKit®-THT

(a)(4). Device Description

The RegenBMC® (RegenKit®-THT-BMC-3-10) is for collection of PRP from peripheral blood and bone marrow for improvement of bone graft handling characteristics. The RegenBMC® device uses thixotropic gel medical device vacuum tubes in conjunction with a clinical centrifuge. The RegenBMC® permits the rapid point-of-care preparation of platelet concentrate from either a small volume of the patient's peripheral blood or a mixture of the patient's peripheral blood and bone marrow. Up to 10mL per tube or 30mL per 3 tube kit of peripheral blood or a mixture of peripheral blood and bone marrow is collected from the patient into the medical device tubes and then spun in a centrifuge according to centrifuge operating instructions. The resulting platelet-rich plasma (PRP) is collected with a syringe and can be used to hydrate various bone grafts, such as demineralized cortical and cancellous grafts, for improved handling.

The RegenBMC® kits contain three (3) RegenTHT® 10 ml tubes (**Figure 1**) which are the main components of the kit. The RegenTHT® 10 ml tubes consist of a sterile pharmaceutical grade glass tube

under vacuum for blood or bone marrow collection. The glass tube contains a thixotropic separator gel (RegenGel-T) composed of a mixture of polymers. (**Figure 2**). The RegenTHT® 10 ml tubes also contain a sodium citrate anticoagulant solution above the separator gel (**Figure 3**). The tubes are closed with a bromobutyl stopper.

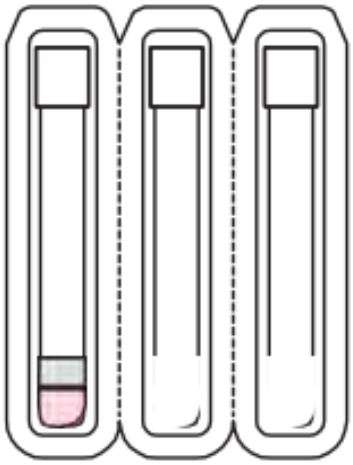
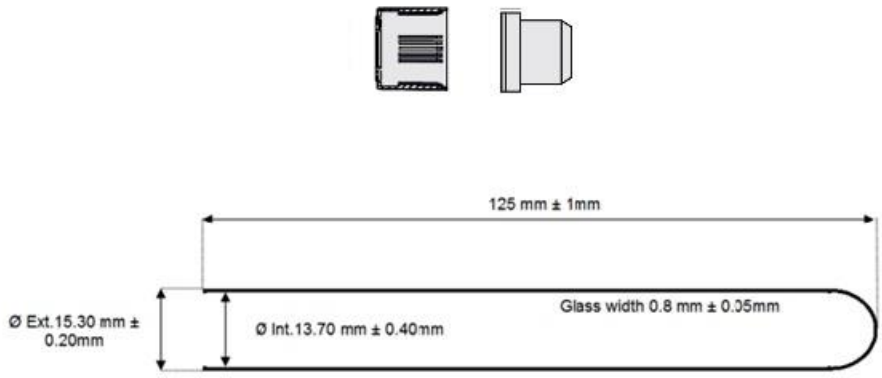


Figure 1. RegenBMC® (RK-THT-BMC-3-10)



1)	Glass tube
2)	Stopper
3)	Cap
4)	Sodium Citrate Solution
5)	Cell separator gel

Figure 2. RegenBMC®

Figure 3. RegenTHT® Tube

If processing peripheral blood only, the peripheral blood sample collected from the patient is transferred into all three tubes and centrifuged in an appropriate centrifuge with specific parameters, as detailed in the device's instructions for use. If processing a mixture of peripheral blood + bone marrow, transfer the mixture into all three tubes. Centrifuge in an appropriate centrifuge with specific parameters, as detailed in the device's instructions for use.

After a portion of the plasma supernatant is removed from each tube [i.e. removal of approximately 3.5 mL of platelet-poor plasma (PPP) from each tube], the re-suspension of the cellular sediment into the remaining 2mL of plasma supernatant in each tube is performed by gently inverting the tube at least 20 times. The resulting 6mL (2mL from each of the three tubes) of platelet-rich plasma (PRP), derived from either peripheral blood or a mixture of peripheral blood and bone marrow aspirate is then ready to be collected into a single syringe using a blood transfer device (syringe and transfer device not included in this kit). The PRP preparation is then ready to be used by the physician to be mixed with autograft and/or allograft bone (to hydrate various bone grafts, such as demineralized cortical and cancellous grafts) prior to application to a bony defect for improved handling characteristics. The PRP should be used in this manner by the physician within four (4) hours from the time of the sample collection.

This 510(k) submission includes packaging testing, sterilization validation, shelf-life/stability validation, and biocompatibility testing according to ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. As an externally communicating – blood path, indirect device with a limited contact duration, the biocompatibility testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity and hemocompatibility testing. This evaluation showed the device is non-cytotoxic, non-sensitizing, a non-irritant, no signs of acute systemic toxicity, non-pyrogenic and hemocompatible. Also included is bench testing, which includes blood cell concentration recovery testing, glass tube mechanical testing, bone graft cohesion testing and device equivalency testing, which supports a substantial equivalence determination.

The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System (BK210655) is the proposed predicate device. Evidence is provided to show the RegenBMC® is substantially equivalent to the predicate device. Based on the indications for use, technological characteristics, safety and performance testing, the RegenBMC® has been shown to be substantially equivalent to Arthrex ACP Max™ PRP System. The RegenKit®-THT (BK090048) device is also presented as a reference device, considering it has the same design and technological characteristics as the RegenBMC®.

(a)(5). Indications for Use

The RegenBMC® system is indicated to be used intraoperatively at the point-of-care for the safe and rapid preparation of autologous platelet concentrate platelet-rich plasma (PRP) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

(a)(6). Technological Characterizes

The RegenBMC® (RK-THT-BMC-3-10) is for collection of PRP from peripheral blood and bone marrow for improvement of bone graft handling characteristics. The RegenKit®-THT-BMC-3-10 permits the rapid point-of-care preparation of platelet concentrate from either a small volume of the patient's blood or a mixture of the patient's blood and bone marrow. The device is design to process up to 10mL per tube or 30mL per 3 tube kit of peripheral blood and/or mixture of peripheral blood and bone marrow which is collected from the patient into the medical device tubes. Peripheral blood or bone marrow is collected from the patient into the medical device tubes and then spun in a centrifuge according to centrifuge operating instructions. The resulting platelet-rich plasma (PRP) is collected with syringes and can be used to hydrate various bone grafts, such as demineralized cortical and cancellous grafts, for improved handling.

The Separator Gel used in RegenBMC® (RegenTHT® tube) is located at the bottom of the tube and remains stable with the following storage conditions: 41°F to 86°F.

Each RegenBMC® tube vacuum is designed to draw approximately 10mL of peripheral blood into each of the three (3) RegenBMC® vacuum tubes. If processing a mixture of peripheral blood and bone marrow, transfer the mixture into all three tubes. Following collection, the peripheral blood or mixture of peripheral blood and bone marrow aspirate is mixed with the anticoagulant by three (3) manual inversions to ensure adequate mixing of the preloaded sodium citrate anticoagulant with the sample. The RegenBMC® tubes are then centrifuged at a relative centrifugal force of 1500g for nine (9) minutes. Following centrifugation, the recovered platelets will be resting on top of the resolidified thixotropic gel layer (with the red blood cells sequestered beneath the gel). The RegenBMC® tube should be gently inverted no less than twenty (20) times, using a "see-saw" motion to resuspend the platelets into the plasma immediately before being transferred into a syringe.

(b)(1). Substantial Equivalence: - Non-Clinical Evidence Performance Data

The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System (BK210655) is the predicate device. The subject device has the same intended use, similar performance characteristics, and has been evaluated against the same performance standards as the predicate device. The RegenBMC® device is biocompatible per ISO 10993-1.

Platelet-Rich Plasma Bioequivalence Testing Using 30mL of Peripheral Blood and a 30mL Mixture of Peripheral Blood and Bone Marrow showed that PRP produced from the RegenBMC® device is equivalent to the predicate device. The Equivalency Testing evaluated the concentrations of platelets, white blood cells (WBC), red blood cells (RBC), and neutrophils at 0 and 4 hours post collection. The Equivalency testing utilized a 20% margin to evaluate equivalence to predicate device. Testing also confirmed the RegenBMC® device has a pH of at least (b) (4) with at least 50% platelet recovery.

Bone Graft Cohesion Testing was performed using PRP produced by the RegenBMC® device from both Peripheral blood and a combination of peripheral blood and bone marrow. Both PRPs improved bone graft handling characteristics, when compared to a saline control, including the ability of the graft to retain the shape of the syringe mold and hardness and handling properties.

Taken together, the data demonstrate that the RegenBMC® device produces PRP from a mixture of peripheral blood and bone marrow in a manner comparable to the predicate device. Supporting data also demonstrate the ability of the device to process PRP consistent with its intended use and improve bone graft handling characteristics. Observed differences between devices are consistent with known technological characteristics and do not alter the intended use or fundamental performance characteristics of the device, supporting a determination of substantial equivalence.

In addition, the subject device allows for equivalent platelet recovery percentage, when processing blood alone, and a higher platelet recovery percentage, when processing blood and bone marrow together, as compared to the predicate device. While these performance differences exist, there is no impact to the ability of the device to improve bone graft handling characteristics. Therefore, the subject device and the predicate device are substantially equivalent.

In addition, the RegenKit®-THT (BK090048) device is used as a reference device since it has the same components as the RegenBMC® device. The table below shows a comparison of the RegenBMC® device to the predicate and reference device to support substantial equivalence.

Comparison of Technology to Predicate Device

Device Name	RegenBMC® (Subject Device)	Arthrex ACP Max™ PRP System (Predicate Device)	RegenKit®-THT (Reference Device)	Comparison
Regulatory Class	Class II	Class II	Class II	Same as Predicate and Reference Devices
510(k) Number	*BK251274*	BK210655	BK090048	Not Applicable
CFR Section	21 CFR 864.9245	21 CFR 864.9245	21 CFR 880.5860	Same as Predicate Device
FDA Product Code(s)	ORG	ORG	FMF	Same as Predicate Device
Manufacturer	RegenLab USA, LLC	Arthrex, Inc.	RegenLab SA	Different manufacturers are listed for the subject device and the predicate device
Intended Use/ Indications for Use	The RegenBMC™ system is indicated to be used intraoperatively at the point-of-care for the safe and rapid preparation of autologous platelet concentrate platelet-rich plasma (PRP) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP system is indicated to be used intraoperatively at the point of care for the safe and rapid preparation of autologous platelet concentrate platelet rich plasma (PRP) from a small sample of peripheral blood or a small sample of a mixture of peripheral blood and bone marrow. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.	The RegenKit®-THT 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 an orthopaedic surgical site as deemed necessary by the clinical use requirements. RegenKit®-THT is for single use only.	Same as Predicate Device
Use Population	Adult populations that can undergo the sample collection process, as deemed safe and reasonable by their physician.	General care patients who are 18 years of age or older	Adult populations who do not have contraindications stated in the instructions for use. The safety and effectiveness have not been evaluated in children or in pregnant or lactating women.	Same as Predicate Device

Device Name	RegenBMC® (Subject Device)	Arthrex ACP Max™ PRP System (Predicate Device)	RegenKit®-THT (Reference Device)	Comparison
Use Environment	Healthcare setting	Healthcare setting	Healthcare setting	Same as Predicate and Reference Devices
Intended User	Trained medical professional	Trained medical professional	Trained medical professional	Same as Predicate and Reference Devices
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Same as Predicate and Reference Devices
Single Use	Yes	Yes	Yes	Same as Predicate and Reference Devices
Principles of Operation	Separation of liquids based on density	Separation of liquids based on density	Separation of liquids based on density	Same as Predicate and Reference Devices
Blood component separation method	Separator gel, anticoagulant solution and centrifugation	Centrifuge with two stage spin and anticoagulant solution	Separator gel, anticoagulant solution and centrifugation	While the blood component separation methods are different between the subject and predicate devices, the RegenBMC® device that has been confirmed biologically safe through biocompatibility testing and effective at producing PRP that improves bone graft handling through performance testing. Performance testing demonstrated that the device produces PRP from both peripheral blood and combination of peripheral blood and bone marrow and that the resulting PRP improves bone graft handling characteristics compared to saline, consistent with the device's intended use. A comparative performance study against the predicate Arthrex ACP Max System confirmed equivalence for key parameters including pH, red blood cell depletion rate, and ADP-activated platelet activation; differences observed in platelet

Device Name	RegenBMC® (Subject Device)	Arthrex ACP Max™ PRP System (Predicate Device)	RegenKit®-THT (Reference Device)	Comparison
				concentration, recovery, white blood cell concentration, and platelet aggregation are attributable to known technological differences between the devices and do not affect the intended use. Taken together, the data support a determination of substantial equivalence, as the observed performance differences do not alter the device's fundamental performance characteristics or its ability to produce PRP suitable for improving bone graft handling characteristics.
Sterility	The device is provided sterile by gamma irradiation	The device is provided sterile by ethylene oxide / gamma irradiation	The device is provided sterile by gamma irradiation	The sterilization is substantially equivalent as both the subject device and the predicate have the same SAL of 10^{-6}. Sterilization validation for the subject device has been completed.
Sterility Assurance Level	SAL 10^{-6}	SAL 10^{-6}	SAL 10^{-6}	Same as Predicate and Reference Devices
Material – Device (not including OEM components)	Tube: Medical grade glass (b) (4) – 125ml Stopper: Bromobutyl Tube Contents: Cell separator gel and Sodium Citrate Solution	Syringe and Piston: Polypropylene, TPE (Thermoplastic Elastomer), Silicone Fluid Cap: Polyethylene HD (High Density) Small Syringe: Polypropylene, Poly-Isoprene Rubber, Silicone Fluid Anticoagulant: Citrate Dextrose A Solution (ACD-A)	Tube: Medical grade glass (b) (4) – 125ml Stopper: Bromobutyl Cap: Medical Polypropylene Tube Contents: Cell separator gel and Sodium Citrate Solution	Similar materials. The RegenKit®-THT (BK090048) device is used as a reference device since it has already been cleared and uses the same components as the RegenBMC® device.

Device Name	RegenBMC® (Subject Device)	Arthrex ACP Max™ PRP System (Predicate Device)	RegenKit®-THT (Reference Device)	Comparison
Volume of Patient Blood Drawn	10mL to 30mL	30mL to 90mL	8mL to 10mL	Similar. The subject device extracts the same or less blood volume from the patient when compared to the predicate device. This difference does not present any new risks or questions on device safety and effectiveness.
Volume of PRP /BMC Generated	6mL	5.3mL	4.72mL	Similar. Performance testing shows that the subject device and the predicate device are substantially equivalent.
Time	Must be used within 4 hours after blood draw	Must be used within 4 hours after blood draw	Must be used within 4 hours after blood draw	Same as Predicate and Reference Devices
Packaging	Kits are packaged in a single-use sterile blister, composed of PETG blister and Tyvek lid	Outer PETG tray with OEM components, Inner PETG tray sealed with Tyvek lid	Kits are packaged in a single-use sterile blister, composed of PETG blister and Tyvek lid	Same as Predicate and Reference Devices
Shelf Life	24 months (2 years)	24 months (2 years)	24 months (2 years)	Same as Predicate and Reference Devices
Performance Testing	Biocompatibility – ISO 10993-1 Blood cell recovery equivalency testing Bone cohesion testing Sterility testing Shelf life/ Stability Testing	Biocompatibility – ISO 10993-1 Blood cell recovery equivalency testing Sterility testing Shelf life/ Stability Testing	Biocompatibility – ISO 10993-1 Sterility testing Shelf life/ Stability Testing	Same as Predicate Device

(b)(2). Substantial Equivalence: - Clinical Evidence

Clinical testing was not necessary for the determination of substantial equivalence.

(b)(3). Substantial Equivalence – Conclusions

The RegenBMC® device is considered substantially equivalent to the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System (BK210655). Based on the indications for use, technological characteristics, and safety and performance testing, the RegenBMC® device has been shown to be appropriate for its intended use and is considered substantially equivalent to the Arthrex Autologous Conditioned Plasma (ACP) Max™ PRP System.