510(k) SUMMARY

I. SUBMITTER

510(k) Holder: OrthoAscent
6151 Thornton Ave Suite 400
Des Moines IA 50321

Contact Person: Jean-Marie Toher
Regulatory Consultant
MEDIcept, Inc.
jtoher@medicept.com

Date Prepared: September 5, 2024

II. DEVICES

Names of Device: FG-001 Platelet Rich Plasma (PRP) Device
Classification Name: Platelet And Plasma Separator For Bone Graft Handling
Regulatory Class: Class II
Product Codes: ORG

III. PREDICATE DEVICES

510(k) Number: BK190317

Applicant: EmCyte Corporation

Device Name: PurePRP SupraPhysiologic Concentrating System

Decision Date: 2/12/2020

IV. DEVICE DESCRIPTION

The FG-001 Platelet Rich Plasma (PRP) Device is a single-use, sterile concentrating device. It concentrates blood components and aids in the separation of the blood components by density using a centrifuge.

The PRP prepared by this device has not been evaluated for any clinical indications. The PRP prepared by this device is NOT indicated for delivery to the patient's circulatory system.

V. INTENDED USE

The FG-001 Platelet Rich Plasma (PRP) Device is designed to be used for the safe and rapid preparation of platelet rich plasma (PRP) from a small sample of blood at the patient's point of care.

VI. INDICATIONS FOR USE

The FG-001 Platelet Rich Plasma (PRP) Device is designed to be used for the safe and rapid preparation of platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft or allograft bone prior to application to an orthopedic surgical site to improve bone graft handling characteristics.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate and the subject device is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences (Table 1).

Table 1. Substantial Equivalence Subject Device PRP Device Compared to the Predicate Device: EmCyte - PurePRP SupraPhysiologic Concentrating System.

Characteristic	Subject Device FG-001 Platelet Rich Plasma (PRP) Device	PurePRP SupraPhysiologic Concentrating System BK190317	Equivalence Comparison
Volume Capacity	60 mL	60 mL	Same
Final Output Volume	7 mL	7 mL	Same
Two Spin Processing	Yes	Yes	Same
Intended Use Statement	The OrthoAscent FG-001 Platelet Rich Plasma (PRP) Device 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 or allograft bone prior to application to an orthopedic surgical site to improve bone graft handling characteristics.	The PurePRP SupraPhysiologic Concentrating 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's point of care. The PRP is mixed with autograft and allograft bone prior to application to an orthopedic surgical site to improve bone graft handling characteristics.	Same
Technology	Centrifugally driven, concentrating device	Centrifugally driven, concentrating device	Same
Sterility Claim	Sterile	Sterile	Same
Shelf Life	1 year	3 years	Different
Principle of Operation	Separation based on density of liquids	Separation based on density of liquids	Same

VIII. PERFORMANCE DATA

Non-clinical performance testing was conducted to verify the subject device performance. The following performance data was provided in support of the substantial equivalence determination.

Performance Testing:
The following testing was conducted based on feedback received in pre-submission BQ220742:

The final finished sterilized device was used for all performance testing.

- Bone graft retention

- pH
- Blood cell count (RBC, WBC);
- Platelet count;
- Platelet recovery;
- Platelet concentration factor;
- P-selectin expression on platelets (on resting and ADP activated platelets); T= 0 & T>4hr
- Hypotonic stress response; T= 0 & T>4hr
- Platelet aggregation (collagen). Extended centrifugation cycle; T= 0 & T>4hr

Statistical equivalency was confirmed for all critical parameters of benchtop testing.

Testing was performed to confirm statistically equivalent extraction/input and injection/output volumes between the subject and predicate device .

Evaluated biocompatibility endpoints per ISO 10993-1 include:

- Interactions with Blood (ISO 10993-4)
- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Systemic Toxicity (ISO 10993-11)
- Pyrogenicity (ISO 10993-12)
- Irritation (ISO 10993-23)

Shelf-life was tested in accordance with ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices and ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems.

Sterility was tested per ISO 13004, ISO 10993-7 and ANSI/AAMI/ISO 11137-2 to achieve a Sterility Assurance Level of 10^{-6}.

IX. CONCLUSIONS

The substantial equivalence tables and performance testing results demonstrate that the Platelet Rich Plasma (PRP) Device and EmCyte PurePRP SupraPhysiologic Concentrating System are substantially equivalent.