510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K070666

B. Purpose for Submission:

Traditional 510(k)

C. Manufacturer and Instrument Name:

Perfusion Partners & Associates, Inc. (C/O Nancy Lord, MD, Esq.), GenesisCS Component Concentrating System

D. Type of Test or Tests Performed:

Centrifuge for clinical use, accessory

E. System Descriptions:

1. Device Description:

   The device is an improved centrifuge tube assembly, which enables blood to be effectively separated and aspirated after they have been centrifuged. This device relates to an apparatus that conveniently sequesters platelet-rich plasma and cell concentrate from bone marrow for use at the point of care.

2. Principles of Operation:

   A sample is introduced into the tubular receptacle of the centrifuge tube assembly causing the aspiration disc to rise through the tubular receptacle as the volume displaces it upwards. The sample is then centrifuged for a desired period of time, e.g. 12 minutes at 1080 Gs. This separates the blood into discrete components, which form layers within the tube, i.e. red blood cells at the lower end, yellow plasma proximate the upper end BMA cells and platelets in the form of a white buffy coat between the red blood cells and plasma. After centrifuging is complete, the plasma is aspirated into a 60 ml syringe, through the aspiration disc and flexible pipe by way of siphoning off the top. This aspiration procedure continues until the buffycoat layer flashes through the flexible aspiration pipe. Once this flash occurs the syringes are changed and the cell buffycoat layer is aspirated in the second syringe.

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2050, General purpose laboratory equipment labeled or promoted for a specific medical use

2. Classification:

   Class I

3 Product code:

   JQC

4. Panel:

   Chemistry (75)

G. Intended Use:

1. Indication(s) for Use:

   The GenesisCS Component Concentrating System is intended to be used in a clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for a preparation of a cell concentrate from bone marrow.

2. Special Conditions for Use Statement(s):

   N/A

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Perfusion Partners & Associates, Inc., Sequire Cell Separator System (K024080)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Principle of Operation	Separation based on density of liquids.	Same

Similarities		
Item	Device	Predicate
Type of Centrifuge Machine:	Non proprietary general purpose, FDA approved.	Same
Table Top	Yes	Same
Refrigerated	No	Same
Swinging Bucket	Yes	Same
Automatic Decanting	No, requires manual aspiration of plasma via aspiration disc.	Same
Micro-processor Controlled	Yes	Same
User Programmable	Yes	Same
Speed Control	Selectable	Same
Acceleration and Braking	Current Controlled	Same
Maximum RPM	2400 RPM	Same
Maximum RCF	1080 G	Same
Tube Capacity	One Disposable 60 ml	Same
Lid Locking Lid Holding	Yes	Same
Balance Detector	Yes	Same
Construction	Anti-torsion construction, metal housing and rotor	Same
Number of Spins	One	Same
Concentrate Fold	Greater than 4 fold	Same

Differences		
Item	Device	Predicate
Indications For Use	Preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for a preparation of a cell concentrate from bone marrow at the point of care.	Preparation of low volume platelet rich plasma, and platelet poor plasma at the point of care.

I. Special Control/Guidance Document Referenced (if applicable):

N/A

J. Performance Characteristics*:*

1. Analytical Performance: N/A

   a. Accuracy:

   b. Precision/Reproducibility:

   c. Linearity:

   d. Carryover:

   e. Interfering Substances:

2. Other Supportive Instrument Performance Data Not Covered Above:

   a. Evaluation for Concentration of Human Bone Marrow Aspirate:

   The analysis (Three study sites) of bone marrow aspirate and bone marrow concentrate consisted of:

   - Complete blood counts utilizing a Medtronic 620-16 parameter hematology analyzer with extended platelet range for total nucleated cells (TNC), platelet count (PLT), and hematopoietic stem cells (HSC);
   - Cytometric analysis of CD34 positive hematopoietic stem/progenitor cells;
   - Manual differential counts on BMA and BMC samples to determine the % of WBC in the TNC count.
   - Yield of nucleated cells, platelets and CD34 positive HSCs were

calculated for bone marrow concentrates.

Summary and Conclusions: The product (BMC) yields wee 76% for TNCs and CD34+ HSC. These yields are consistent with other point of care bone marrow concentrating devices as per the medical literature. Platelet yields in the BMC averaged 70% and the product hematocrit averaged 31.6% with a range of 31-40%.

b. Evaluation of Platelet Recovery and In Vitro Characteristics on Platelets from Whole Blood:

Platelet in vitro characteristics (i.e. pH p-selectin, platelet aggregation and hypotonic stress) were evaluated at time) (immediately after processing) and at time +4 hours (4 hours post-processing) in order to assess in vitro quality.

Conclusions: Data from this study has demonstrated that platelet concentrations in the platelet concentrate product were high with an average of greater than 9 times baseline. The platelet yield was also high, averaging greater than 60% over a varying range of baseline platelet counts. The yields and platelet concentrations compare favorably with other commercial CPP systems as per the medical literature.

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.