SPECIAL 510(K): DEVICE MODIFICATION
OIR DECISION SUMMARY

510(k) Number: K183205

This 510(k) submission contains information/data on modifications made to the applicant's own class II or class I devices requiring 510(k). The following items are present and acceptable:

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1. The name and 510(k) number of the applicant's previously cleared device: GenesisCS Component Concentrating System, K070666.

2. Applicant's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   This change was for the addition of a Self-Sealing Needleless Valve Port to the Flat Base, extension of the Flat Base external perimeter, addition of an O-ring to the Sealing Piston Diaphragm and increase in the inner and outer diameters of the Device Container and Device Cap.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics.

   The differences between the subject device and predicate are the following: 1) The Self-Sealing Needless Valve port has been added to the flat base to provide an additional inlet/outlet port at the lower end of the device to facilitate the second spin of the processing step by which aspirated bone marrow and cell concentrate buff-coat are reintroduced into the device for final processing; 2) The External Perimeter of the Flat Base has been increased to prevent the self-sealing valve port from contacting the underlying surface when standing upright; 3) The Sealing Piston Diaphragm has been modified with a larger outer diameter and an additional O-Ring seal to ensure that solution added to the interior of the device from the base port is contained and does not transmit around the seal during centrifugation; and 4) The Device Container and Device Cap has a larger inner diameter and outer diameter to allow the device to maintain a processing capacity equivalent to the predicate device.

5. A **Design Control Activities Summary** which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

      The risk estimation and risk evaluation determined for each identified risk is based on the Risk Management, ISO 14971:2012. A high level risk analysis and probability of occurrence were provided in Leak Detection Test Summary Report (Appendix A), Tensile Testing on Plastic

Welds (Appendix B) and Dimension Inspection Test (Appendix C). In conclusion, no further mitigation is required for these modifications.

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria was applied and found to be satisfactory. No safety risks were introduced. Description of the verification and validation activities were provided for the PureBMC SupraPhysiologic Concentrating System. System level test protocols, including pass/fail criteria, sterilization validation and regression analysis for bone marrow samples with nucleated cell counts and platelet counts were also provided and met the predefined acceptance criteria.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the applicant's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The applicant has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.