**PLATELET RICH PLASMA**

**510(k) Number: BK050055**

**Device Name:** GenesisCS Component Concentrating System

**Indications for Use:** The GenesisCS Component 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 can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.

**510(k) Number: BK190317**

**Device Name:** PurePRP SupraPhysiologic Concentrating System

**Indications for Use:** 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.

**510(k) Number: KO24080**

**Device Name:** SECQUlRE Cell Separator

**Indications for Use:** The SECQUIRE cell separator is designed for the safe and effective preparation of low volume platelet rich plasma, and platelet poor plasma at the point of care.

**BONE MARROW ASPIRATE CONCENTRATE**

**510(k): K07066**

**Device Name:** GenesisCS Component Concentrating System

**Indication for Use:** The GenesisCS Component Concentrating System is designed 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.  The safety and effectiveness of this device for in vivo indications for use has not been established.

**510(k): K183205**

**Device Name:** PureBMC SupraPhysiologic Concentrating System

**Indication for Use:** The PureBMC SupraPhysiologic 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 concentrate and cell concentrate from a small sample of bone marrow aspirate. The safety and effectiveness of this device for in vivo indications for use has not been established.

**ADIPOSE**

**510(k): K191564**

**Device Name:** Progenikine Concentrating System

**Indications for Use**: The Progenikine Concentrating System is used in medical procedures involving the harvesting and transferring of autologous adipose tissue. The Progenikine® Concentrating System is used for concentrating adipose tissue harvested with a legally marketed lipoplasty system. The Progenikine Concentrating System is intended for use in the following surgical specialties when the concentration of harvested adipose tissue is desired. Neurosurgery, Gastrointestinal Surgery, Urological Surgery, Plastic and Re-constructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Laparoscopic Surgery, Arthroscopic Surgery.