

US Regulatory Profile

The following is provided as a reference regarding the regulatory status of the SmartPREP[®] Centrifuge System (510k numbers K991430, BK000037, and K052925) and the Graft Delivery System (510k number K043261)

SmartPREP 2 Bone Marrow Processing

The SmartPREP 2 Centrifuge System is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate from a small sample of blood and for preparation of cell concentrate from bone marrow.

* Warning: The safety and effectiveness of this device for in-vivo indications for use has not been established.

Harvest Graft Delivery System

The Harvest Graft Delivery System is intended for the aspiration of bone marrow, autologous blood, plasma, or other fluids. The system is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with the aspirate(s), I.V. Fluids, blood, plasma, platelet rich plasma, bone marrow, or other specific blood component(s) as deemed necessary by the clinical use requirements.