

The following is provided as a reference regarding the regulatory status of the SmartPReP<sup>®</sup> Platelet Concentrate System (510k numbers K991430 and BK000037) and the SmartJet<sup>™</sup> Liquid Applicator (510k numbers K000456, K011032, and K020252).

## **Regulatory Classification**

### SmartPReP Platelet Concentrate System

The SmartPReP Platelet Concentrate System has been formally classified by the FDA as a Class I device.

### SmartJet Liquid Applicator

The SmartJet Liquid Applicator has been formally classified by the FDA as a Class II device.

## **Indication(s)**

### SmartPReP Platelet Concentrate System - Bone

The SmartPReP Platelet Concentrate System is designed to be used for the safe and rapid preparation of autologous platelet concentrate from a small sample of blood at the patient's point of care. The APC can be mixed with autograft or allograft bone grafting material prior to application as deemed necessary by the clinical use requirements.

The process makes available APC for mixing with bone grafting materials for delivery to the intended site using a bone graft delivery syringe or other suitable mixing containers (e.g. bone grafting material mixing cup). The APC helps improve the handling characteristics of the bone graft material, facilitates fixation of the bone graft material to the intended surgical site and may help optimize conditions for healing (increasing the concentration of platelets at the graft site above native levels may also help to optimize the conditions for healing as platelets' natural physiologic function is to release proteins that can promote cell migration).

### SmartJet Liquid Applicator – Bone and Soft Tissue

The SmartJet Applicator is designed to allow for the simultaneous delivery of two different liquids to the same site.

The SmartJet Applicator is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site, with IV fluids, autologous blood, plasma, platelet rich plasma, or other specific blood component(s) as deemed necessary by the clinical use requirements.

The SmartJet Applicator is intended for the application of fluids, as deemed necessary, by the surgeon's determination of the clinical use requirements, to facilitate the preparation of soft tissue autograft or allograft material prior to the application of graft material to a repair site.

## **Method of Regulation and Compliance**

The Federal Food, Drug, and Cosmetic Act general controls provisions require annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The SmartPReP Platelet Concentrate System and the SmartJet Liquid Applicator are manufactured in accordance with the FDA's requirements for medical devices found in 21 Code of Federal Regulations (CFR), Title 21, Parts 800 to 895 and in compliance with the current Good Manufacturing Practices as set forth in the Quality System Regulations (QRS) for medical devices

Sincerely,



Jack Bonasera  
Director, Regulatory Affairs and Quality Assurance

**Developing Technologies for Accelerating Healing, Naturally<sup>™</sup>**