

510(k) Summary

Holding Technologies' Maximus Processing System Blood PRP Kit

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Device Trade Name:	Maximus Processing System Blood PRP Kit
Common or Usual Name:	Platelet or plasma separator
Classification Name:	Platelet and Plasma Separator for Bone Graft Handling (21 CFR 864.9245)
Predicate Device:	Arthrex Angel Concentrated Platelet Rich Plasma (cPRP) System (BK110046)

Intended Use / Indications for Use

Holding Technologies' Maximus Processing System ("Maximus PS") Blood PRP Kit is indicated to be used intraoperatively at the point of care for the safe and rapid preparation of autologous platelet concentrate (platelet rich plasma or PRP) from a small sample of peripheral blood. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.

Technological Characteristics / Principles of Operation

The Maximus Processing System Blood PRP Kit consists of a sterile, disposable processing kit with a single-use Maximus disposable for the preparation of platelet rich plasma (PRP). The Maximus PS Blood PRP Kit includes an accessory kit containing single-use sterile components for blood collection. The Maximus disposable is designed to be processed on a non-sterile reusable centrifuge.

The Maximus Processing System Blood PRP Kit separates and concentrates platelets from a small sample of the patient's blood. The patient's sample is collected into syringes preloaded with anticoagulant citrate dextrose solution, formula A ("ACDA") and transferred to the Maximus disposable device. The Maximus device is a centrifuge tube with an internal bifurcated piston, similar in shape to an hourglass with a central, graduated cylinder. The loaded Maximus device is centrifuged for 10 minutes and the patient's hematocrit, or 'cell layer', forms in the graduated cylinder. The internal piston of the Maximus device can be slightly adjusted up or down to center the patient's

hematocrit on a preset indicator line, where a second 3-minute adjustment centrifuge cycle clarifies the cell layer before the PRP is isolated. The PRP is drawn from the Maximus disposable and is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.

Performance Data

Holding Technologies has conducted performance testing to demonstrate the Maximus Processing System Blood PRP Kit and the predicate device are similar with respect to blood cell and platelet concentrations, platelet recovery in the PRP, and pH. In all instances the Maximus Processing System Blood PRP Kit functioned as intended and the platelet concentrations were as expected. Red blood cell concentrations were reduced to similar levels in both PRP systems. With respect to the white blood cell content of the PRP, the Maximus Processing System Blood PRP Kit achieved the intended concentration but was slightly higher than the predicate device and this does not impact the clinical use of the concentrated platelets for mixing with autograft and/or allograft bone. Holding Technologies has also performed platelet functional testing in the product of both the Maximus Processing System Blood PRP Kit and predicate devices, specifically platelet aggregation, hypotonic shock response, and P-selectin expression in a 'No Device' control and the PRP product from both devices. In all platelet functional testing the results were within acceptance criteria of the performance of platelets collected from the predicate device at the relevant time points.

Substantial Equivalence

Holding Technologies' Maximus Processing System Blood PRP Kit is as safe and effective as Arthrex Inc.'s Angel Concentrated Platelet Rich Plasma (cPRP) System. The Maximus Processing System Blood PRP Kit has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Maximus Processing System Blood PRP Kit and its predicate device, including the centrifuge disposable disk, the slower centrifuge speed, and the optical selection of the buffy coat, raise no new issues of safety or effectiveness. Performance data demonstrate that the Maximus Processing System Blood PRP Kit is as safe and effective as the Arthrex Angel System. Thus, the Maximus Processing System Blood PRP Kit is substantially equivalent to the predicate.