

DATE: 1/27/12

FROM: [REDACTED]

SUBJECT: P050044/S019
Vitagel™ Surgical Hemostat/Stryker, Corp.

CONTACT: Ms. Catherine Moffa

TO: **THE RECORD**

BACKGROUND/ REASON FOR SUPPLEMENT

P050044/S019 is a 180-Day Supplement that requests FDA approval for a design change (removal of the metering knob) to the CellPaker component of the Vitagel Surgical Hemostat system, introduction of a new contract manufacturer, a change to the packaging materials and sterilization methods, and the re-branding of the CellPaker component as VitaPrep Plasma Separator.

REVIEW TEAM

[REDACTED]

INDICATIONS FOR USE

Vitagel™ is indicated in surgical procedures (other than neurosurgical and ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

DEVICE DESCRIPTION

Vitagel Surgical Hemostat is composed of a suspension of bovine collagen and bovine thrombin, which, when combined with the patient's plasma, forms a safe and effective hemostat. Vitagel Surgical Hemostat includes the following components and/or accessories:

- Vitagel Syringe – an [REDACTED] (b) (4) filled, sterile syringe containing a suspension of bovine collagen, bovine thrombin, and calcium chloride
- Transfer Syringe – a sterile empty syringe used following collection of autologous human plasma (using the CellPaker accessory)
- Delivery System – an apparatus designed to combine and mix the contents of the Vitagel Syringe with the patient's plasma contained in the transfer syringe at the time of administration to the bleeding site. The product's delivery system is comprised of:
 - A joiner to connect the Vitagel Syringe to the Transfer Syringe

- A spray head incorporating a mixer element
 - A cannula incorporating a mixer element (provided as an alternate delivery component to the spray head)
 - A syringe clip to permit the depression of the plunger rods of the two syringes simultaneously
 - A syringe support to aid the surgeon in holding the assembled device
- CellPaker Plasma Collection Device – a sterile blood collection accessory containing [REDACTED] (b) (4)
[REDACTED] It is used to separate plasma from whole blood via centrifugation.
 - Tabletop Centrifuge

PRECLINICAL/BENCH

DESIGN VERIFICATION

Plasma Volume

The sponsor provided data from a plasma volume study using porcine blood in order to demonstrate that the VitaPrep device reliably produces the required amount of plasma ($\geq 4.5\text{mL}$). The study compared the amount of plasma obtained from five CellPaker and five VitaPrep devices. The results indicate that equivalent volumes of distinguishable plasma are produced with either device.

Platelet Concentration

A human blood platelet study was conducted in order to evaluate the concentration of blood platelets within the plasma following centrifugation. Twelve 30 mL samples per device were evaluated. Results indicate that both devices perform equivalently in regards to platelet concentration factor and platelet percent yields.

Syringe Performance

A study was performed using methods described in ISO 7886-1:1993, *Sterile Hypodermic Syringes for Single-Use: Part 1 – Syringes for Manual Use*, to compare the VitaPrep device to an off-the-shelf 12 mL syringe control with respect to air leakage, liquid leakage, and force required to operate. For all samples of both the test and control article, there was no evidence of air leakage, no observed fall in the manometer reading, and no detachment of the piston from the plunger during the course of testing. Similarly, there was no evidence of liquid leakage from either VitaPrep or control devices. VitaPrep syringes performed equivalently or better than control syringes during force to operate testing.

BIOCOMPATIBILITY

The biocompatibility of VitaPrep was evaluated according to the requirements of ISO 10993-1: 2009 and FDA guidelines for an externally communicating device with limited (<24 hours) indirect blood path contact. All test results met the requirements outlined in the relevant sections of ISO 10993.

