Cytomedix, Inc.
Angel® Concentrated Platelet Rich Plasma (cPRP) System
510(k) Summary – BK110046
October 2012

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Device Trade Name: Angel® Concentrated Platelet Rich Plasma (cPRP) System

Common/Usual Name: *Platelet and plasma separator for bone graft handling*

Classification Name: *Platelet and plasma separator for bone graft handling* (21 CFR 864.9245)

Predicate Device: The Magellan™ Autologous Platelet Separator System (K021902, BK040068, BK030040)

Device Description:

The Cytomedix Angel® Concentrated Platelet Rich Plasma (cPRP) System consists of a blood centrifugation device and associated disposable processing set and whole blood access kit. The device is intended to be used at the patient's point-of-care for the safe and rapid preparation of platelet poor plasma and platelet rich plasma from a small sample of whole blood or a small mixture of blood and bone marrow. The platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site as deemed necessary by the clinical use requirements.

The Blood Access Kit contains syringes, needles, anticoagulant, and a site preparation kit for collecting the blood and bone marrow to be processed with the Angel® cPRP System. The Processing Set utilizes a variable volume separation chamber that separates autologous whole blood and bone marrow into red blood cells, platelet poor plasma, and platelet rich plasma. The Processing Set is provided sterile with a non-pyrogenic fluid pathway, and is for single patient use only. The Processing Set consists of the pre-connected variable volume separation chamber, a tubing set with a platelet sensor/valve assembly, and a three-compartment reservoir bag to hold the blood products (whole blood, red blood cells, and platelet poor plasma). A syringe is provided to collect the platelet rich plasma.

The primary features of the Angel® cPRP System hardware are the centrifuge well and lid, roller pump, platelet sensor, valve assembly driver, touch screen user interface, and emergency stop switch. The platelet sensor detects the presence of the separated blood components as they exit the variable volume separation chamber, and switches the position of a rotating valve in the Processing Set to channel the individual blood components into their respective collection containers.

Statement Of Technical Characteristics Comparison

A comparison of device features and test data demonstrate that the Angel® Concentrated Platelet Rich Plasma (cPRP) System is substantially equivalent to the currently marketed Arteriocyte Magellan Autologous Platelet Separator System.

510(k) Number (if known)_____BK110046_____

Device Name: Angel® Concentrated Platelet Rich Plasma (cPRP) System

INDICATIONS FOR USE:

To be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of whole blood or a small mixture of blood and bone marrow. The platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.

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