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510(k) Summary of Safety and Effectiveness

**OrthoPAT™¹ Perioperative Autotransfusion System
K962475**

Submitter:

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Device Name:

Classification name: Autotransfusion Apparatus

Proprietary Name: OrthoPAT™ Perioperative Autotransfusion System

Predicate Devices:

The OrthoPAT Perioperative Autotransfusion System is substantially equivalent to the Electromedics PAT 500 Portable Autotransfusion System (K910238), the IBM Model 2991 Blood Cell Processor (K812355), and the Solco-Basle Solcotrans® SI Orthopedic Autotransfusion Set (K913177).

¹ OrthoPAT is a trademark of Transfusion Technologies Corporation

Device Description:

The OrthoPAT™ system consists of a single-use disposable set and an electromechanical device. The patient's blood is contained within the disposable set, is used for both intraoperative and postoperative processing (concentration and washing) of shed blood. The concentrated red blood cells are deposited into a bag. The bag is removed from the OrthoPAT system prior to the blood being reinfused.

The electromechanical device controls the collection process, the separation and washing process and the flow of fluids through the disposable. It contains a centrifuge, a pneumatic system, a valve system, electronic circuitry, a rechargeable battery, software for monitoring and controlling the operation of the system, and a separately-mounted display panel with a control keypad.

The system is compact, light weight, can be mounted on an IV pole or bed frame, and is designed to follow the patient from the operating room, to the recovery room, and, if necessary, to the hospital floor. The on-board rechargeable battery provides power to the system to maintain suction while the patient is being transported. The system functions automatically without a dedicated operator.

Intended Use:

The OrthoPAT™ Orthopedic Perioperative Autotransfusion System is intended for use in major orthopedic surgical procedures, such as joint replacement or spinal fusion to salvage red blood cells lost during and after surgery. It processes the shed blood to separate and wash the red blood cells (RBCs) and make them available for autologous transfusion to the patient.

Basis for Claim of Substantial Equivalence:

Transfusion Technologies Corporation claims its OrthoPAT Orthopedic Perioperative Autotransfusion System to be substantially equivalent to the Electromedics PAT 500 Portable Autotransfusion System (K910238), the IBM Model 2991 Blood Cell Processor (K812355), and the Solco-Basle Solcotrans® SI Orthopedic Autotransfusion Set (K913177) based on the following:

Intended Use

The OrthoPAT system and the Electromedics PAT 500 system are intended to collect and concentrate shed blood lost during surgery. The OrthoPAT system and the Solco-Basle system are intended to collect and reinfuse blood lost postoperatively.

Design

The OrthoPAT system and the Electromedics PAT 500 system are a combination of hardware, software and sterile disposables.

In both systems, the shed blood is stored in a sterile collection reservoir until the blood is processed. The red blood cells are concentrated by centrifugation and stored in a bag for subsequent reinfusion to the patient.

The materials used in the disposable sets of both systems are well accepted in the industry for this application

The OrthoPAT system does not utilize air to move fluids within the disposable set, and therefore does not require an air sensor to detect the end of an emptying cycle. In addition, a variable volume rotor moves fluid through the disposable set by way of an elastic diaphragm, which expands and contracts by external air pressure or vacuum. This design eliminates the need for a peristaltic pump. The movement of fluid by an elastic diaphragm is substantially equivalent to the flexible membrane used by the IBM Model 2991.

Performance data

An in vitro simulation of use test of the OrthoPAT system demonstrated the quality of blood product produced by it. Total cell recovery ranged from 79% to 88%. Washout efficiency of contaminants ranged from 95% to 100%. This performance is substantially equivalent to the Electromedics PAT 500 system.