

3/30/99

K 982660

Transfusion Technologies Corp.

510(k) Summary of Safety and Effectiveness

OrthoPAT™¹ Perioperative Autotransfusion System

Submitter:

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Contact person: John J. Sokolowski

Date Prepared:

July 27, 1998

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.



MAR 30 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John J. Sokolowski
Vice President, Quality Assurance
and Regulatory Affairs
Transfusion Technologies Corporation
9 Erie Drive
Natick, MA 01760-1312

Re: K982660
OrthoPAT™ Perioperative Autotransfusion System
Regulatory Class: II (Two)
Product Code: 74 CAC
Dated: January 11, 1999
Received: January 12, 1999

Dear Mr. Sokolowski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

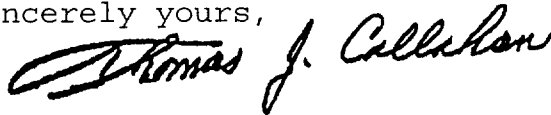
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

