K122262

510(k) Summary

Date: July 26, 2012

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Submitter:
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Device Information:
Trade Name: Haemonetics OrthoPAT advance Perioperative Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC

Predicate Device Information:
Trade Name: Haemonetics OrthoPAT Perioperative Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC

Device Characteristics Summary:
The OrthoPAT advance Perioperative Autotransfusion System is an evolution of the previously cleared OrthoPAT Perioperative Autotransfusion System. The OrthoPAT Perioperative Autotransfusion System was most recently cleared via 510(k) K992723 on October 18, 1999.

The OrthoPAT advance System is designed to salvage Red Blood Cells (RBCs) from blood lost intraoperatively and postoperatively during surgical procedures where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to two liters per hour.

Blood shed from the surgical site or wound drain is collected in the reservoir; processed in the Dynamic Disk® separation chamber to pack the RBCs; washed to remove the cell fragments, irrigation fluid, plasma, and other undesirable components that are found in the fluid portion of the shed blood; then transferred to a bag for gravity reinfusion to the patient.

The OrthoPAT advance System consists of the following three parts that work together to collect and process the RBCs lost during and after surgery:

- OrthoPAT advance device: the electro-mechanical device and display screen.
- Disposable set: the single-use collection material including reservoir, processing set, A&A line, post-op line, and vacuum line.
- Solutions: solutions for collecting and processing salvaged blood (examples: anticoagulant and wash solutions).

The OrthoPAT advance device, together with the disposables to be used with the device, is the subject of this 510(k) submission.

Non-Clinical Testing Summary:
The following non-clinical performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the performance testing is presented below in **Table 1: Summary of Performance Studies.** Test data demonstrates that the device met all clinical and performance requirements, and that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Table 1: Summary of Performance Studies

Test Name	Test Report #	Test Intent	Test Result
Bench Testing for Software	TR-SOF-100367 TR-SOF-100377 TR-SOF-100378	The intent of these studies was to validate an update to the software user interface with display of Estimated Blood Loss (EBL) volume.	Passed
Biocompatibility Testing for Reservoir	TR-BIO-100023-A	The intent of this study was to demonstrate the biocompatibility of the new reservoir, containing materials different from the predicate device.	Passed
Transportation & Aging Testing for Reservoir	TR-ACG-100094AA TR-DIS-101222A TR-DIS-101338	The intent of these studies was to demonstrate the package integrity and device stability of the new reservoir, up to a six month shelf life.	Passed
Bench Testing for Electrical Hardware	TR-ELE-100445	The intent of this study was to demonstrate the electrical safety of the increased-capacity battery.	Passed
EMC	TR-ELE-100445A	The intent of this testing was to demonstrate the EMC compliance of the modified device.	Passed

Comparison to Predicate Summary:
The OrthoPAT advance Perioperative Autotransfusion System is an evolution of the OrthoPAT Perioperative Autotransfusion System. The OrthoPAT Perioperative Autotransfusion System was most recently cleared via 510(k) K992723 on October 18, 1999. The OrthoPAT advance System is designed to perform the same types of procedures as the previously-cleared OrthoPAT system, utilizing identical disposable sets as well as additional disposables designed for the new system. The changes from the previously-cleared OrthoPAT System to the subject OrthoPAT advance System include a software user interface update, a change in reservoir material and orientation of the reservoir filter, and an increase in battery capacity.

A summary of the OrthoPAT advance System comparison to the predicate OrthoPAT System is presented in Table 2: **Comparison of the OrthoPAT advance System to the Previously-Cleared Predicate OrthoPAT System.**

Table 2: Comparison of the OrthoPAT advance System to the Previously-Cleared Predicate OrthoPAT System

	Predicate OrthoPAT Device (K992723)	**Subject OrthoPAT advance Device**
Indications for Use	The Haemonetics OrthoPAT (Perioperative AutoTransfusion) System is indicated for use to salvage Red Blood Cells (RBCs) from blood lost intraoperatively and postoperatively during surgical procedures where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to 2 liters per hour. Autotransfusion is indicated for patients who meet at least one of the following criteria: • The patient is expected to lose sufficient blood in the perioperative period so as to require RBC transfusion, and autotransfusion will likely reduce or eliminate the need for allogeneic blood transfusion. • Religious beliefs cause the patient.to refuse allogeneic transfusion, but accept autologous transfusion. • Compatible allogeneic blood is not available. • The patient is unable to donate sufficient quantities of autologous blood prior to surgery to adequately cover the anticipated transfusion requirement. • The patient or physician prefers perioperative autotransfusion rather than preoperative autologous donation or transfusion of allogeneic blood.	Same

Table 2 (cont.):

	Predicate OrthoPAT Device (K992723)	Subject OrthoPAT advance Device
Hardware Device:		
Display unit		
• Keypad	Contains seven membrane switches and corresponding LED indicator lights	Contains thirteen buttons that provide pressed status to the display processor. Seven of the buttons shall provide associated key lights that can be turned on and off by software The SELECT button shall provide three key lights associated with it that can be turned off by the Display Processor
• Display	LCD (480x640 pixel)	Same
Base Unit		
• Centrifuge	0 to 5500 rpm Pneumatic control of disposable disk diaphragm	Same
• Header Arm	The header arm holds the header portion of the disk stationary during operation	Same
• Red blood cell sensor	Light source and sensor to differentiate between air, waste, fluid, and red blood cells	Same
• Spill containment system	Spill containment well and spill containment ring	Spill containment well drain and spill collection bag
Rotary Valves		
• Inlet Valve	Controls the flow of fluid into the disk	Same
• Effluent Valve	Controls the flow of fluid out of the disk	Same
Pneumatic System		
• Vacuum	0 to -350mmHG [0 to -39.99 kPA; 0 to -399.9 mbar]	Same
• Pressure	0 to 250mmHG [0 to 33 kPA; 0 to 333 mbar]	Same
• Pump	Maintains selected vacuum range	Same
Reservoir Optics System		
• Light Bar	Emits light towards the light reflector located in the reservoir	Same
• CCD Camera	Tracks the movement of the float and monitors the fluid level of the reservoir	Same
Power Supply		
• AC Power	AC power accommodates worldwide voltage and frequencies from 100V to 240V, 50/60Hz	Same
• Battery power	Nickel Metal hydride 7.2 volts and provides 1800mAH	Lithium Ion 8.4V 4600mAH
Rear panel	Provides mechanism for mounting an IV pole and supports the display unit	Same

Table 2 (cont.):

	Predicate OrthoPAT Device (K992723)	Subject OrthoPAT advance Device
Software		
• Base Unit	Controls device subsystems such as pneumatics, centrifuge, reservoir, etc.	New software for the CD camera calibration and detection algorithm; Added memory storage area for calibration data, machine recovery information data, and procedure summary and event data
• Display Unit	Control LCD display, keypad, key lights, and tone generator	Additional functionality utilizing a new keypad to add AC volume, process volume trigger, process time trigger, interval timer reset and display toggling between graphic and text messages; A new audible alarm will be generated and a visual text message will be displayed when the reservoir volume reaches the process volume trigger volume or process time trigger set by operator; Additional icons will be generated and displayed for use with the battery and charging system
Disposables:		
Integrated Processing Set	Collects blood in reservoir, processes blood from collection reservoir and separates into RBC's and waste	Designed to use Quickconnect collection reservoir and processing set.
• Anticoagulant line	Delivers anticoagulant to shed blood	Component of Aspiration and Anticoagulation line
• Anticoagulant Roller Clamp	Allows the operator to adjust the flow rate of the anticoagulant	Component of Aspiration and Anticoagulation line
• Anticoagulant Spike	Incorporates a drip chamber to allow the operator to visually monitor the anticoagulant flow rate	Component of Aspiration and Anticoagulation line
• Anticoagulant Y Adapter	Allows the anticoagulant to flow into the aspiration line and mix with the blood as it flows toward the reservoir	Component of Aspiration and Anticoagulation line
• Aspiration Connector	Connector to either the wound drain set or the intraoperative suction set	Component of Aspiration and Anticoagulation line
• Aspiration Line	Connects the suction tip or wound drain to the reservoir	Same
• Effluent Stopcock	Diverts fluid from the rotor into either the waste bag or the RBC bag	Same
• Inlet Stopcock	Diverts fluid into the rotor from either the reservoir or the saline bag	Same
• Saline line	Runs between inlet stopcock and saline spike	Same
• Separation Chamber (rotor, disk)	Spins in the centrifuge to separate the shed blood and process the RBCs	Same
Aspiration and Anticoagulant line HAR-A-1003	N/A	Connects suction tip to reservoir, anticoagulates shed blood
• Anticoagulant Roller Clamp	N/A	Allows the operator to adjust the flow rate of the anticoagulant

Table 2 (cont.):

	Predicate OrthoPAT Device (K992723)	Subject OrthoPAT advance Device
• Anticoagulant Spike	N/A	Incorporates a drip chamber to allow the operator to visually monitor the anticoagulant flow rate
• Anticoagulant Y Adapter	N/A	Allows the anticoagulant to flow into the aspiration line and mix with the blood as it flows toward the reservoir Material: PVC
Aspiration and Anticoagulant line 1400T	Connects suction tip to reservoir, anticoagulates shed blood	Same
• Anticoagulant Roller Clamp	Allows the operator to adjust the flow rate of the anticoagulant	Same
• Anticoagulant Spike	Incorporates a drip chamber to allow the operator to visually monitor the anticoagulant flow rate	Same
• Anticoagulant Y Adapter	Allows the anticoagulant to flow into the aspiration line and mix with the blood as it flows toward the reservoir Material: PVC	Same
Post-op Suction set	Connects to wound drain tubing and collects blood postoperatively from wound drain	Same
Reservoir	Serves four functions: Transmission of vacuum, storage of salvaged blood, filtration of salvaged blood, and fluid volume measurement	Same
• Body	Material: ABS Plastic	Material: Polycarbonate SABIC HP4R
• Cover	Material: ABS Plastic	Material: Polycarbonate Lexan HP4NR with 8H9D266 White
• Mesh filter	Removes clots and large debris from the shed blood Material: ABS frame frame/copolyester mesh	Material: Polypropylene Frame: TOTAL 3620 WZ Screen: Polyester, Saati PES 200/43 with Plasma Treatment
• Hydrophobic Filter	Material: PVDF sheet	Frame: HP4R Filter: 1um ePTFE, CVL-HC1 with Pre-Filter 4.3 um HOVOGLAS HC4011
• Grommet	Material: Silicone rubber	OrthoPAT advance does not use a grommet
• Float ball	Floats on the blood as it fills the reservoir, monitored by reservoir light bar. Material: Polypropylene GR2	Material: Polypropylene Plasma treated then pad printed with MARIBU TPU 980 Black
• Light reflector	Material: ABS with white clariant	Same Material: ABS Terlux 2802 HD with white clariant UN0001
• Tubing	Material: PVC	Same
• Pre-filter	Capture and retain debris as fluid enters the reservoir Material: Thermally reticulated polyester/polyurethane foam	OrthoPAT advance does not use a Pre-Filter

Table 2 (cont.):

	Predicate OrthoPAT Device (K992723)	Subject OrthoPAT advance Device
• Straw	Pulls fluid from the bottom of the reservoir Material: PVC	Same
• Reservoir Ports	Shorts line which end in a connector Material: PVC	Same
• Aspiration connector	Polypropylene	Component of A&A Line HAR-A-1003 Anticoagulant Y Adapter
• Relief Valve	Not a part of the system	Additional part assembled to cover for connection to outlet line or reservoir Silicone Vernay PN VL1001M12
Waste bag	Stores the waste fluid and saline wash that are separated from the concentrated RBCs PVC	Same
RBC bag	Stores the concentrated RBCs for transfusion back to the patient PVC	Same
Sterilization	Gamma	EtO
Shelf Life		
• Processing Set		
○ 1150H (Integrated)	3 years	N/A – See below for OPT-P-1000
○ OPT-P-1000	N/A	3 years
• HAR-A-10003	N/A	3 years
• 1400T	3 years	3 years
• Post-op Suction Set	3 years	Same
• Reservoir	N/A	6 months
• Waste Bag	3 years	Same
• RBC Bag	3 years	Same

Erica Diaz

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Haemonetics Corporation

7-26-12
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 25 2012

Haemonetics Corporation
c/o Ms. Erica Diaz
Regulatory Affairs Specialist
355 Wood Road
Braintree, MA 20184

Re: K122262
OrthoPAT advance system Perioperative Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: July 26, 2012
Received: July 27, 2012

Dear Ms. Diaz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Haemonetics OrthoPAT advance (Orthopedic Perioperative Autotransfusion) System

Indications for Use:

The Haemonetics OrthoPAT advance (Orthopedic Perioperative Autotransfusion) System is indicated for use to salvage Red Blood Cells (RBCs) from blood lost intraoperatively and postoperatively during surgical procedures where the expected rate of processing of salvaged blood and fluid aspirated from the surgical site is less than or equal to 2 liters per hour. Autotransfusion is indicated for patients who meet at least one of the following criteria:

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- Religious beliefs cause the patient to refuse allogeneic transfusion, but accept autologous transfusion.
- Compatible allogeneic blood is not available.
- The patient is unable to donate sufficient quantities of autologous blood prior to surgery to adequately cover the anticipated transfusion requirement.
- The patient or physician prefers perioperative autotransfusion rather than preoperative autologous donation or transfusion of allogeneic blood.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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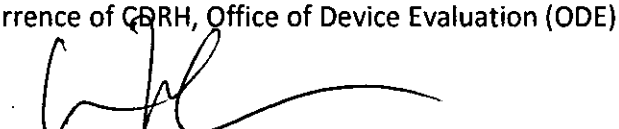
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122762