510(k) Summary K101907

Date Prepared: November 22, 2010

Submitter:
Haemonetics Corporation
400 Wood Road.
Braintree MA 02184

DEC - 3 2010

Contact:
Greg Calder
Regulatory Affairs Specialist
Phone: 781-356-9538
Fax: 781-356-3558 fax
Email: gcalder@haemonetics.com

Device Information:
Trade Name: Haemonetics Cell Saver Elite 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 Cell Saver 5 Autologous Blood Recovery System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC

Device Characteristics Summary:
The Cell Saver Elite Autotransfusion System is an evolution of the Haemonetics Cell Saver 5 Autologous Blood Recovery System. The Cell Saver 5 was most recently cleared via 510(k) K014083.

The Cell Saver Elite System is intended to be used by trained physicians, operating room nurses or floor nurses, anesthesia technicians and autotransfusion service providers to provide intra-operative and post-operative blood salvage for surgical procedures with medium to high blood loss including, but not limited to CABG, AAA, joint replacement, spinal, trauma and transplant surgeries.

The Cell Saver Elite System consists of a single use disposable set and reusable equipment. One disposable set is used throughout an individual patient's surgical procedure and then discarded. The Cell Saver Elite System utilizes a unique bowl processing kit, but is compatible with Haemonetics standard reservoirs and A&A lines.

The collected blood is processed through a centrifugal separation chamber (bowl) where RBCs are concentrated and then washed, removing unwanted substances such as hemolized cells, anticoagulant and irrigating fluids. The washed RBC product is available for return via a product bag to the patient.

The Elite System is designed to perform plasma sequestration using the autotransfusion disposable in conjunction with an ancillary sequestration set prior to performing autotransfusion.

Non-clinical Testing Summary:
Non-clinical performance testing was completed in accordance with AT6:2005. A summary of the performance testing is presented below in **Table 1: Summary of Performance Studies**. Test data demonstrates that the device and resultant blood products met all clinical and performance requirements, and is as safe, as effective, and performs as well as or better than the predicate device.

Table 1: Summary of Performance Studies

Cell Saver Elite In-house Laboratory Evaluation of Processing Efficiency and RBC Recovery	TR-CLN-100177	The intent of this study was to characterize the performance of the Cell Salvage protocol of the CS Elite in terms of processing efficiency and product characteristics.	• Final product hematocrit of 40-60% • Heparin Washout ≥95% • Free Hemoglobin Washout ≥95% • Red Blood Cell Recovery ≥80% **Conclusion:** **Data met Acceptance Criteria**
In-house Laboratory Validation of Platelet Sequestration Protocol Using the Cell Saver Elite	TR-CLN-100201	The intent of this study was to evaluate the Platelet Sequestration protocol of the CS Elite in terms of performance and product characteristics	No formal acceptance criteria; characterization of the product. **Conclusion:** The platelet rich plasma that is produced meets the threshold of three (3) times the incoming platelet count of the whole blood.
In-house Laboratory Evaluation of Processing Efficiency and Product Characteristics using Pools without Lysate	TR-CLN-100049	The intent of this study was to characterize the performance of the Cell Salvage protocol of the CS Elite in terms of processing efficiency and product characteristics of blood without Lysate; and therefore to confirm the true red cell recovery.	• Final product hematocrit of 40-60% • Heparin Washout ≥95% • Free Hemoglobin Washout ≥95% • Red Blood Cell Recovery ≥80% **Conclusion:** **Data met Acceptance Criteria** The data above indicate the processed RBC product data from all three bowl types exceeded the acceptance criteria in terms of Hematocrit, RBC Recovery and Washout. The RBC recovery data was, on average 12% higher than the RBC Recovery derived from procedures using pools with high levels of free hemoglobin.

Comparison to Predicate Summary:
The Cell Saver Elite system is an evolution of the Haemonetics Cell Saver 5 Autologous Blood Recovery System. The Cell Saver 5 system was most recently cleared via 510(k) K014083. The Cell Saver Elite system is designed to perform the same types of procedures as the Cell Saver 5 system, utilizing very similar disposable sets. The primary changes from the Cell Saver 5 to the Cell Saver Elite systems include a modernized graphical user interface with a touch screen display, barcode data capture capability to simplify data entry, and the integration of an onboard vacuum system to provide regulated vacuum to the collection reservoir.

A summary of the Cell Saver Elite system comparison to the predicate Cell Saver 5 system is presented in **Table 2: Comparison of the Haemonetics Cell Saver Elite system to the predicate Cell Saver 5 system.**

Table 2: Comparison of the Haemonetics Cell Saver Elite System to the Predicate Cell Saver 5 System

Characteristic	Cell Saver Elite System (Subject device)	Cell Saver 5 System (Predicate most recently cleared K014083)
Indications for Use	The Haemonetics Cell Saver® Elite™ Autotransfusion System and its related accessory components are intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping this processed red cell product to either a bag for gravity reinfusion into the patient or to the arterial line of an extracorporeal circuit for reinfusion into the patient. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within 6 hours of collection.	The Cell Saver 5 Autologous Blood Recovery System is intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping this processed red cell product to either a bag for gravity reinfusion into the patient or to the arterial line of an extracorporeal circuit for reinfusion into the patient. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within 6 hours of collection.
Disposable Set	Designed to utilize the Latham 225 ml bowl, Latham 125 ml bowl, and Blow Molded 70 ml bowl processing sets. Designed to utilize the PRP/PPP Sequestration disposable accessory.	Designed to utilize the Latham 225 ml bowl, Latham 125 ml bowl, and Blow Molded 70 ml bowl processing sets. Designed to utilize the PRP/PPP Sequestration disposable accessory.
User Interface	Graphical User Interface with touch screen display technology for device interface. Integrated barcode scanner to simplify data entry. Beacon light on top of the display to provide general device status at a glance. The status indicator and message area on the GUI each have a vertical color coded bar that corresponds to the beacon light.	LCD display with discrete keys for device interface.

Table 2 (cont): Comparison of the Haemonetics Cell Saver Elite to the Predicate

Characteristic	Cell Saver Elite System (Subject device)	Predicate Cell Saver 5 System (Cleared K932890, K014083)
Processing Functionality	Cell Salvage protocol: Fill Wash Empty Concentrate Return Emergency mode (Latham processing sets only) Sequestration protocol: Fill Empty Concentrate	Cell Salvage protocol: Fill Wash Empty Concentrate Return Emergency mode (Latham processing sets only) Sequestration protocol: Fill Empty Concentrate
Centrifuge	Holds the rotating portion of the Latham bowls during a procedure. For the 70 ml Blow Molded bowl, a chuck adaptor is used to hold the rotating portion of the bowl in the centrifuge. Centrifuge speeds are defined for each protocol and bowl type.	Holds the rotating portion of the Latham bowls during a procedure. For the 70 ml Blow Molded bowl, a chuck adaptor is used to hold the rotating portion of the bowl in the centrifuge. Centrifuge speeds are defined for each protocol and bowl type.
Pump	A three-roller occlusive pump moves fluids into and out of the bowl. Pump speeds are defined for each phase.	A three-roller occlusive pump moves fluids into and out of the bowl. Pump speeds are defined for each phase.
Bowl Optics	The bowl optics assembly is mounted within the centrifuge. The optics assembly possesses two optical sensors; one for Latham bowls and one for Blow Molded bowl.	The bowl optics assembly is mounted within the centrifuge.
Effluent Line Sensor	Monitors quality of bowl effluent (eg. wash is satisfactory), adjusts pump speed (eg. avoid red cell spillage), and advances system to next phase when appropriate.	Monitors quality of bowl effluent (eg. wash is satisfactory), adjusts pump speed (eg. avoid red cell spillage), and advances system to next phase when appropriate.
Valve Module	Consists of three pinch valves, which are used to direct flow of fluids through the set, and a manifold pressure sensor, which monitors pressure levels in blue-striped and red-striped lines during Empty and Return.	Consists of three pinch valves, which are used to direct flow of fluids through the set and a clamped line sensor, which monitors pressure levels in blue-striped and red-striped lines during Empty and Return.
Air Detector	Ultrasonic air detector monitors fluid flow in the pump tubing. In Fill, the sensor detects air when reservoir is empty. In Concentrate, the sensor detects air when RBC bag is empty. During Wash, it senses air when saline bag is empty. In Empty and Return, it senses air when bowl is empty.	Ultrasonic air detector monitors fluid flow in the pump tubing. In Fill, the sensor detects air when reservoir is empty. In Concentrate, the sensor detects air when RBC bag is empty. During Wash, it senses air when saline bag is empty. In Empty and Return, it senses air when bowl is empty.

Table 2 (cont): Comparison of the Haemonetics Cell Saver Elite to the Predicate

Characteristic	Cell Saver Elite System (Subject device)	Predicate Cell Saver 5 System (Cleared K932890, K014083)
Waste Bag Weigher	Load cell based sensor used to monitor the amount of fluid collected in the 10 L waste bag. When ~ 7.5 L of fluid is detected, the device displays a message that the waste bag is almost full. When ~ 8.5 L of fluid is detected, the device displays a message that the waste bag is full.	Load cell based sensor used to monitor the amount of fluid collected in the 10 L waste bag. When ~ 8 L of fluid is detected, the device displays a message that the waste bag is almost full. When ~9 L of fluid is detected, the device displays a message that the waste bag is full. For the 70 ml processing set: When ~ 4 L of fluid is detected, the device displays a message that waste bag should be emptied. When ~ 4.5 L of fluid is detected, the device displays a message that the waste bag is full.
Reservoir Weigher	Load cell based sensor used to track the amount of fluid collected in the reservoir. The device initiates Fill depending upon the values set for Fill start volume and Fill resume volume.	Load cell based sensor used to track the amount of fluid collected in the reservoir. The device initiates Fill depending upon the values set for Fill start volume and Fill resume volume.
Suction	Designed to work with both regulated external suction, and onboard manual and SmartSuction technology.	Designed to work with regulated external suction.
Historical Procedure Data	Designed to provide historical procedure records that include procedure data and optional consumable data. Consumable data can be entered via an onboard barcode scanner or typed directly into the record. The procedure records can be downloaded onto a USB storage device. The device can retain data for up to 100 procedures.	Designed to provide a limited procedure summary that can be viewed on the display.

Greg Calder

Date: 11/22/2010

Greg Calder
Regulatory Affairs Specialist
Haemonetics Corporation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Haemonetics Corporation
c/o Mr. Greg Calder
400 Wood Road
Braintree, MA 02184-9114

DEC - 3 2010

Re: K101907
Trade/Device Name: Haemonetics Cell Saver Elite Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: II
Product Code: CAC
Dated: November 22, 2010
Received: November 29, 2010

Dear Mr. Calder:

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

Enclosure

Indications for Use

DEC - 3 2010

510(k) Number (if known): K101907

Device Name: Haemonetics Cell Saver® Elite™ Autotransfusion System

Indications For Use: The Haemonetics Cell Saver® Elite™ Autotransfusion System and its related accessory components are intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping this processed red cell product to either a bag for gravity reinfusion into the patient or to the arterial line of an extracorporeal circuit for reinfusion into the patient. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within 6 hours of collection.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Richmond

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101907