DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 23, 2016

Haemonetics Corporation
Mark Anzalone
Regulatory Affairs Specialist
400 Wood Road
Braintree, MA 02184

Re: K160197
Trade/Device Name: Haemonetics Cell Saver Elite Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: May 17, 2016
Received: May 18, 2016

Dear Mr. Anzalone:

This letter corrects our substantially equivalent letter of May 24, 2016.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160197

Device Name
Haemonetics Cell Saver Elite Autotransfusion System

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date: March 4th, 2016

Submitter:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

Contact:
Mark Anzalone
Regulatory Affairs Specialist
Phone: 781-356-9912
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Email: mark.anzalone@haemonetics.com

Device Information:

Trade Name:	Haemonetics Cell Saver Elite Autotransfusion System
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Device Class:	2

Device Characteristics Summary:
The subject of this Special 510(k) is the Haemonetics Cell Saver Elite Autotransfusion System fat washing protocol and modified 70mL bowl algorithm.

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.

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.

Intended Use:
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.

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. Test data demonstrates that the device met all performance requirements, and that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

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Table 1: Summary of Performance Studies

Test Name	Test Report #	Test Intent	Test Result
Software Validation	TR-SOF-100562	To validate fat washing protocol in revision AK of the CS Elite software.	Passed
Software Validation	TR-SOF-100565	To validate revision AL of the CS Elite software.	Passed
Functional Testing	TR-OTH-100649	To verify CS Elite 70 mL bowl performance	Passed
Functional Testing	TR-OTH-100647	To verify CS Elite blood washout performance with fat washing protocol.	Passed
Functional Testing	TR-OTH-100641A	To verify the performance of the CS Elite fat washing protocol.	Passed
Functional Testing	TR-OTH-100646	To verify CS Elite blood washout performance.	Passed

Comparison to Predicate:
The Haemonetics Cell Saver Elite Autotransfusion system with fat washing protocol and modified 70mL bowl algorithm is substantially equivalent to the Cell Saver Elite Autotransufsion system cleared in K120586. The Cell Saver Elite is intended for use with the same hardware and disposables as the predicate device and in the same operating environment with the same donor/operator population. The indications for use are the same. The technological characteristics of the subject device differ from the predicate only in the addition of the fat washing feature and modifications to the 70mL bowl algorithm. These differences do not render the device non-substantially equivalent because non-clinical testing has demonstrated that the subject device is as safe and effective as the predicate and the results of verification and validation have not raised different questions of safety and effectiveness than the predicate.

Sorin XTRA PFAT program is provided as a reference device only for comparison of the fat reduction program to the subject device.

A summary comparison is presented below in Table 2.

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Table 2: Comparison of the Cell Saver Elite Software revision AL to the Predicate Cell Saver Elite Software Revision AD

	Predicate **Cell Saver Elite System (K120586)**	**Subject** **Cell Saver Elite System with software revision AL**	**Reference Device** **Sorin Xtra (K131553)**
Manufacturer	Haemonetics Corporation	Same	N/A
Trade Name	Haemonetics Cell Saver Elite	Same	N/A
Common Name	Automated Blood Cell Separator	Same	N/A
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same	N/A
Regulation Number	21 CFR 864.9245	Same	N/A
Product Code	CAC	Same	N/A
Device Class	2	Same	N/A
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.	Same	N/A
Discussion	*The devices have the same Indications for Use and the proposed changes to not expand the previously cleared Indications for Use.*		

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	Predicate **Cell Saver Elite System (K120586)**	**Subject** **Cell Saver Elite System with software revision AL**	**Reference Device** **Sorin Xtra (K131553)**
Intended Use	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.	Same	N/A
Discussion	*Both devices have the same intended use. The addition of fat washing and the modified 70 mL bowl do not impact the intended use of the device, only improve upon existing functionality.*		
Disposables	There were no changes to the Cell Saver Elite disposables associated with the changes that are the subject of this 510(k) application.	Same	N/A
Discussion	*The disposables used with the Cell Saver Elite device have not changed.*		
Processing Functionality	**Cell Salvage protocol:** Fill Wash Empty Concentrate Return Emergency mode (Latham processing sets only)	Same	N/A
	Sequestration protocol: Fill Empty Concentrate	Same	N/A
	Cell Salvage protocol acceptance criteria: HCT% ≥ 40% RBC Recovery ≥ 80% Plasma HgB Washout ≥ 95% Heparin Washout ≥ 95% Albumin Washout ≥ 95%	Same	N/A

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	Predicate Cell Saver Elite System (K120586)	Subject Cell Saver Elite System with software revision AL	Reference Device Sorin Xtra (K131553)
	Fat Washing Protocol N/A	**Fat Washing Protocol: (New to subject device)** Fill Fat Wash • Return • Fill • Wash • Empty • Fill • Wash Empty Concentrate Return	**PFAT** • Removal of fat particles • Excellent supernatant removal • Good Hematocrit
	Fat Washing Protocol Acceptance Criteria: N/A	**Fat Washing Protocol Acceptance Criteria:** HCT% ≥ 40% RBC Recovery ≥ 80% Plasma HgB Washout ≥ 95% Heparin Washout ≥ 95% Albumin Washout ≥ 95% Fat Removal ≥ 99%* *depending on bowl size used	**Fat Removal Performance:** Fat Particles Removal >99%*** HCT ≈ 50%*** Heparin, Protein, Albumin, Potassium >95%*** *** "Fat removal during cell salvage – An optimized program in the XTRA® autotransfusion device" Timo Seyfried, MD, Michael Gruber, MD; Lilith Haas; Ernil Hansen, PhD, MD 13th ECOPEAT Vienna - Austria 2013
Discussion	*Both devices have similar processing capabilities. The Cell Saver Elite with revision AL software adds the Fat Washing protocol which will function in a similar manner to the existing Cell Salvage protocol as described in Section 4 - Device Description. Both the Cell Salvage protocol and the proposed Fat Washing protocol will both use the same technological characteristic described below to operate. The Fat Washing protocol is optimized to remove additional fat during the wash phase and will not introduce any new concerns for safety or effectiveness as shown through testing summarized in Table 1 above. The key device performance characteristics for the cell salvage protocol and the fat washing protocol remain the same when compared to the predicate device.* *The proposed Fat Washing protocol discussed through this 510(k) can be seen in other cleared devices. One such reference device is Sorin Xtra Autotransfusion System (K131553). The Sorin Xtra has a PFAT process which has similar performance characteristics to the proposed Fat Washing protocol.*		

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	Predicate Cell Saver Elite System (K120586)	Subject Cell Saver Elite System with software revision AL	Reference Device Sorin Xtra (K131553)
Graphical 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.	Same	N/A
Software	Software Revision 4.0 (AD)	Software Revision 7.0 (AL)	N/A
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.	Same	N/A
Pump	A three-roller occlusive pump moves fluids into and out of the bowl. Pump speeds are defined for each phase.	Same	N/A
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.	Same	N/A
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.	Same	N/A
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.	Same	N/A

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	Predicate **Cell Saver Elite System (K120586)**	**Subject** **Cell Saver Elite System with software revision AL**	**Reference Device** **Sorin Xtra (K131553)**
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.	Same	N/A
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.	Same	N/A
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.	Same	N/A
Suction	Designed to work with both regulated external suction, and onboard manual and SmartSuction technology.	Same	N/A
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.	Same	N/A
Discussion	*All device technological characteristics remain the same between the Predicate and Subject device with the exception to the software, which has added fat washing and the modified 70 mL bowl algorithm. The technological characteristics that differ between the predicate and subject device do not raise any new concerns for safety or effectiveness.*		

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4 - Mar - 2016

Mark Anzalone
Regulatory Affairs Specialist
Haemonetics Corporation

Date