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

January 03, 2017

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

Re: K162423
Trade/Device Name: Haemonetics Cell Saver Elite/Elite+ Autotransfusion System
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: December 2, 2016
Received: December 5, 2016

Dear Mark Anzalone:

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" (21 CFR 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 D. Zuckerman, M.D.
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)*
K162423

Device Name
Haemonetics Cell Saver Elite/Elite+ Autotransfusion System

Indications for Use *(Describe)*
The Haemonetics Cell Saver® Elite/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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date: December 21st, 2016

Submitter:
Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

Contact:
Mark Anzalone
Regulatory Affairs Specialist
Phone: 781-356-9912
Fax: 781-356-3558
Email: mark.anzalone@haemonetics.com

Device Information:

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

Primary Predicate:

Trade Name:	Haemonetics Cell Saver Elite Autotransfusion System
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Clearance Number:	K160197
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Device Class:	2

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Device Characteristics Summary:
The subject of this Special 510(k) is the Haemonetics Cell Saver Elite/Elite+ Autotransfusion System software and hardware to enable use of wired and wireless connectivity.

The Cell Saver Elite/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/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/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/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/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/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 substantially equivalent to the predicate device.

Table 1: Summary of Performance Studies

Test Name	Test Report #	Test Intent	Test Result
Electromagnetic Compatibility	TR-ELE-100782	To verify compliance with EMC requirements per IEC 60601-1-2	Pass
Electrical Safety	TR-ELE-100812	To verify compliance with electrical safety requirements per IEC 60601-1	Pass
Wireless Coexistence	TR-ELE-100786	To verify wireless coexistence of the CS Elite/Elite+ with potential interference appliances	Pass
Software Validation	TR-SOF-100592	To validate version AN of the CS Elite/Elite+ Software	Pass

Comparison to Predicate:
The Haemonetics Cell Saver Elite/Elite+ Autotransfusion system with wireless connectivity is substantially equivalent to the Cell Saver Elite/Elite+ Autotransufsion system cleared in K160197. The Cell Saver Elite/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 connectivity feature through software and modified User Interface (UI) hardware. These differences do not render the device non-substantially equivalent because non-clinical testing has demonstrated that the device met all performance requirements, and that the subject device is substantially equivalent to the predicate device.

A summary comparison is presented below in Table 2.

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Table 2: Comparison of the Cell Saver Elite/Elite+ with connectivity to the Predicate Cell Saver Elite Software version AL

	Predicate **Cell Saver Elite System (K160197)**	**Subject** **Cell Saver Elite/Elite+ System with connectivity**
Manufacturer	Haemonetics Corporation	Same
Trade Name	Haemonetics Cell Saver Elite	Add Haemonetics Cell Saver Elite+
Common Name	Automated Blood Cell Separator	Same
Classification Name	Separator, Automated, Blood Cell, Diagnostic	Same
Regulation Number	21 CFR 864.9245	Same
Product Code	CAC	Same
Device Class	2	Same
Indications for Use	The Haemonetics Cell Saver® Elite/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
Discussion	*The previously cleared device and proposed device have the same Indications for Use and the proposed changes do not expand the previous cleared Indication for Use.*	

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	Predicate Cell Saver Elite System (K160197)	Subject Cell Saver Elite/Elite+ System with connectivity
Intended Use	The Cell Saver Elite/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
Discussion	*The previously cleared device and proposed device have the same Intended Use. The addition of the connectivity feature does not impact the intended use of the device.*	
Disposables	There were no changes to the Cell Saver Elite/Elite+ disposables associated with the changes that are the subject of this 510(k) application.	Same
Discussion	*The proposed modifications do not impact the disposables used with the Cell Saver Elite/Elite+ device.*	
Software	Software Version 7.0 (AL)	Software Version 7.1 (AN) • Fix open software anomalies • Update software to allow communication with an approved server application
Discussion	The proposed modifications will add new networking features to the Cell Saver Elite/Elite+ device. This new feature will allow the device to transmit data from the device to an approved server application and receive device settings and software updates from an approved server application. The software modifications will not affect substantial equivalence to the predicate device since performance requirements will not be affected. Additionally, data can already be exported via a USB stick on the predicate device, the proposed modification will allow the user additional convenience for exporting existing data.	

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	Predicate Cell Saver Elite System (K160197)	Subject Cell Saver Elite/Elite+ System with connectivity
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.	Graphical User Interface and beacon light will remain the same as the predicate device User Interface hardware updated: • Add wireless module • Update single board computer to support wireless module • Update barcode scanner from 1D scanning to 2D scanning • Modify housing to support RJ45 Ethernet port
Discussion	*The proposed modifications to the User Interface hardware is a more modern single board computer, which will allow support for the wireless module. The modified device will remain substantially equivalent to the predicate device since the device will continue to meet existing performance requirements.*	

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	Predicate Cell Saver Elite System (K160197)	Subject Cell Saver Elite/Elite+ System with connectivity
Processing Functionality	Cell Salvage protocol: Fill Wash Empty Concentrate Return Emergency mode (Latham processing sets only) Sequestration protocol: Fill Empty Concentrate Fat Washing Protocol: Fill Fat Wash • Return • Fill • Wash • Empty • Fill • Wash Empty Concentrate Return	Same
Discussion	*The processing capabilities will remain the same between the proposed device and predicate device.*	

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	Predicate Cell Saver Elite System (K160197)	Subject Cell Saver Elite/Elite+ System with connectivity
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
Pump	A three-roller occlusive pump moves fluids into and out of the bowl. Pump speeds are defined for each phase.	Same
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
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
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
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
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

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	Predicate Cell Saver Elite System (K160197)	Subject Cell Saver Elite/Elite+ System with connectivity
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
Suction	Designed to work with both regulated external suction, and onboard manual and SmartSuction technology.	Same
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
Discussion	*The technological characteristics of the device remain the same between the Predicate and Subject device with the exception of the modified UI hardware and the connectivity feature in software version AN. The technological characteristics that differ as a result of the proposed modifications do not render the device not substantially equivalent.*	

Mark Anzalone
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Haemonetics Corporation

21-Dec-2016
Date