November 15, 2022

Haemonetics Corporation
Ergang Alexis
Director Regulatory Affairs
125 Summer Street
Boston, Massachusetts 02110

Re: K221722
Trade/Device Name: Haemonetics Cell Saver Elite/Elite+ Autotransfusion System (CSE-E-US/CSE-EW-US)
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: October 14, 2022
Received: October 14, 2022

Dear Ergang Alexis:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221722

Device Name
Haemonetics Cell Saver Elite/Elite+ Autotransfusion System (CSE-E-US/CSE-EW-US)

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 the processed red blood cells to a product bag. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within the recommended time guidelines of the American Association of Blood Banks (AABB), 9th Edition.

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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HAEMONETICS®

510(k) Summary

Date: November 15, 2022

Submitter:
Haemonetics Corporation
125 Summer Street
Boston, MA 02110

Contact:
Alexis Ergang
Director, Regulatory Affairs
Phone: 224-244-2850
Email: alexis.ergang@haemonetics.com

Device Information:

Trade Name:	Haemonetics Cell Saver Elite/Elite+ Autotransfusion System (CSE-E-US/CSE-EW-US)
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Device Class:	2

Predicate Device Information:

Trade Name:	Haemonetics Cell Saver Elite/Elite+ Autotransfusion System (CSE-E-US/CSE-EW-US)
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Device Class:	2
510k Number:	K162423

Reference Device Information:

Trade Name:	Medtronic autoLog IQ Autotransfusion System
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830

HAEMONETICS®

Product Code:	CAC
Device Class:	2
510k Number:	K181954
Trade Name:	Xtra Autotransfusion System
Common Name:	Autotransfusion Device
Classification Name:	Autotransfusion Apparatus
Regulation Number:	21 CFR 868.5830
Product Code:	CAC
Device Class:	2
510k Number:	K131553

Device Characteristics Summary:
The subject of this Traditional 510(k) is the Haemonetics Cell Saver Elite/Elite+ Autotransfusion System 7.3 (AQ) software update which allows users the ability to manually control the cell salvage procedure through manual mode, quick transfer and decreased minimum wash volume.

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 the processed red blood cells to a product bag. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within the recommended time guidelines of the

American Association of Blood Banks (AABB), 9th Edition.

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.

Table 1: Summary of Performance Studies

Test Name	Test Report #	Test Intent	Test Result
Software Verification	TR-SOF-100792	To verify the AQ revision of the Cell Saver Elite/Elite+ software	Passed
Software Verification	TR-SOF-100769	To verify the AQ revision of the Cell Saver Elite/Elite+ software	Passed
Functional Testing	TR-OTH-101003	To validate Cell Saver Elite/Elite+ washout performance	Passed
Usability Testing	TR-OTH-101010	To validate the operational needs and usability of the Cell Saver Elite/Elite+	Passed

Comparison to Predicate:
The Haemonetics Cell Saver Elite/Elite+ Autotransfusion system with 7.3 (AQ) software is substantially equivalent to the Cell Saver Elite/Elite+ Autotransufsion system cleared in K162423. 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 have been clarified for the Cell Saver Elite/Elite+. The proposed modifications to the Indications for Use and the proposed software changes do not expand or change the safety profile from the previous cleared Indication for Use. The Intended Use for the Cell Saver Elite/Elite+ is the same between the subject and predicate device. The technological characteristics of the subject device differ from the predicate only in the new embedded software, which includes new features for manual control of the cell salvage procedure. These differences do not impact the clinical functionality of the device and do not render the device non-substantially equivalent. The non-clinical and clinical testing has demonstrated the subject device is as safe and effective as the predicate device. The results of the testing have not raised different questions of safety and efficacy from the predicate.

A summary comparison is presented below in Table 2.

Table 2: Comparison of the Cell Saver Elite/Elite+ Software with 7.3 (AQ) Software to the Predicate Cell Saver Elite/Elite+ Software version 7.1 (AN)

	Predicate **Cell Saver Elite/Elite+ System (K162423)**	**Subject** **Cell Saver Elite/Elite+ System with 7.3 Software**
Manufacturer	Haemonetics Corporation	Same
Trade Name	Haemonetics Cell Saver Elite/Elite+	Same
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™ 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 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 the processed red blood cells to a product bag. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion to the same patient within the recommended time guidelines of the American Association of Blood Banks (AABB), 9th Edition.

	Predicate Cell Saver Elite/Elite+ System (K162423)	Subject Cell Saver Elite/Elite+ System with 7.3 Software
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
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
Software	Software Revision 7/0 (AN)	Software Revision 7.3 (AQ)
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, with updates to help and on screen information

	Predicate **Cell Saver Elite/Elite+ System (K162423)**	**Subject** **Cell Saver Elite/Elite+ System with 7.3 Software**
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, with the addition of manual mode, quick transfer, and modification of the range selection for minimum wash volume. These modifications provide the users to manually control the cell salvage procedure.
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	Same

	Predicate Cell Saver Elite/Elite+ System (K162423)	Subject Cell Saver Elite/Elite+ System with 7.3 Software
	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.	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
Reservoir Weigher	Load cell based sensor used to track the amount of fluid collected in the reservoir. The device initiates Fill	Same

	Predicate Cell Saver Elite/Elite+ System (K162423)	Subject Cell Saver Elite/Elite+ System with 7.3 Software
	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.	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

Conclusion:
The summary of the data, included in this submission, is sufficient to show that the Haemonetics Cell Saver Elite/Elite+ Autotransfusion System is substantially equivalent to the legally marketed predicate device, the Haemonetics Cell Saver Elite/Elite+ Autotransfusion System.