

## SECTION 5 510 (K) Summary

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**Classification:** 21 CFR § 864.9195, Class II

**Classification name:** Blood mixing devices and blood weighing devices

**Product Code:** MYJ

**Trade Name:** HemoMix 3 with DCSX software

**Generic/Common Name:** Device, Mixing And Weighing, Semi-Automated

### **Predicate device**

Predicate Device: MacoMix HM20 and Hemolog 6  
510(k) Number: BK160095  
510(k) Clearance Date: November 15, 2017  
Regulation Number: 21 CFR 864.9195  
Regulation Name: Blood Mixing Devices and Blood Weighing Devices  
Regulatory Class: II  
Product Code: MYJ

### **Indications for use**

HemoMix 3 with optional DCSX Software is an automated blood monitor/mixer used during blood donation to mix the anti-coagulant contained in the blood bag with the whole blood collected during donation and automatically clamping the tube when the target volume has been reached

### **Product Description**

HemoMix 3 with optional DCSX Software is an automated blood monitor/mixer used during blood donation to mix the anti-coagulant contained in the blood bag with the whole blood collected during donation and automatically clamping the tube when the target volume has been reached.

HemoMix 3 with DCSX consist of two parts: the HemoMix 3 device and optional DCSX software.

HemoMix 3 is a mechanical mixer that mixes continuously the blood with the anticoagulant inside the bag, visualizes the collected volume, the elapsed time and the average flow, it checks continuously that the flow is within a minimum

## SECTION 5 510 (K) Summary

and a maximum value, it monitors that the collection ends within a settable time and it stops when a set volume is reached (or when a maximum time is elapsed). The mechanical mixing is controlled by a DC motor with its gearbox, resulting in a gentle oscillation of the tray which moves on an orbital trajectory. Clamping and monitoring the blood collection are made due to a weight measurement system and an electromagnetic clamp. The HemoMix 3 automatically clamps the collection line and the volume manually program by the operator volume calculated using the optional DCSX software.

HemoMix 3 is able to manage bidirectional communication from/to a host PC. It can read barcodes and RFID tags sending data to a PC (via cable or via wireless option mode) or store onto a memory card or a USB stick. The collection HemoMix 3 parameters can be set locally on the device and / or can be programmed by an external application (DCSX software). The collection process is managed by a dedicated microcontroller. Once the target volume has been reached during the collection a locking clamp, which press on the tube stopping the blood flow, and an acoustic and visual signaling to the operator are activated. HemoMix 3 is not classified as a weighing instrument, the weight shown on the display is an informative value.

### **Comparison of Technological Characteristics**

The comparison table of technological characteristics is documented in the following table Predicate Device Comparison.

**SECTION 5**  
**510 (K) Summary**

**TABLE: Predicate Device Comparison**

Substantial Equivalence	Model Characteristic	HemoMix 3 and DCSX Subject Device	MacoMix HM20 and Hemolog 6 Predicate Device
	<b>GENERAL</b>		
	<b>Product Code</b>	MYJ	Same
	<b>Common Name</b>	Blood Mixer	Same
	<b>Regulation Number</b>	864.9195	Same
	<b>Regulation Description</b>	Blood mixing and blood weighing device	Same
	<b>Submission Type</b>	510(k) Traditional	Same
	<b>510(k) Number</b>	NA	BK160095
	<b>Purpose</b>	To replace manual mixing of whole blood collection with automated mixing	Same
	<b>Intended Use</b>	Automated blood mixer used during blood donation to mix the anti-coagulant contained in the blood bag with the whole blood collected during donation and automatically clamping the tube when the preset target volume has been reached	Same
	<b>Principle of operation</b>	Controlled by a motor, resulting in a gentle oscillation of the tray	Same
	<b>Where Used</b>	Fixed or mobile whole blood collections	Same
	<b>Classification</b>	Device	Same
	<b>Power Source</b>	115/230 Vac or internal rechargeable battery	100-240 Vac or internal rechargeable battery
	<b>Battery</b>	Ni-Mh, 12 Vdc	Same
	<b>Battery Autonomy</b>	Up to 70 donations	Up to 90 donations
	<b>Barcode Reader</b>	Yes, removable	Same
	<b>Instruments Status Information</b>	In real-time	Same
	<b>Data Storage</b>	Internal	Same
	<b>Wireless Modem</b>	Optional	Same

**SECTION 5**  
**510 (K) Summary**

Substantial Equivalence	Model Characteristic	HemoMix 3 and DCSX <u>Subject Device</u>	MacoMix HM20 and Hemolog 6 <u>Predicate Device</u>
	<b>Transmission of Data</b>	Bidirectional, wireless or wired connection	Same
	<b>Useful Life</b>	5+ years	Same
	<b>Tube clamp</b>	Yes, frontal	Same
	<b>Control Panel</b>	LCD display, back lit	Same
	<b>Warning</b>	A red light as well as an audible warning indicate an anomaly during whole blood collection. Audible warning can be adjusted by the operator or switched off.	Red light as well as an audible and visual alarm indicate an anomaly during whole blood collection
	<b>Measurements unit</b>	Milliliters (ml) preset density of the blood as 1.052 gr /ml, adjustable by the operator	Milliliters (ml) taking into account the density of the blood as 1.06 gr / ml
	<b>Endpoint</b>	Stops mixing and clamps the tubing at the target volume	Stops mixing and clamps the tubing at the target volume
	<b>Blood Bag Suitability</b>	All types	Same
	<b>Automatic Tare</b>	Yes	Same
	<b>Internal Data Storage</b>	Yes (up to 1024 collections)	Yes (up to 210 collections)
	<b>Weight</b>	3 kg without packaging and without battery pack	2.9 kg without packaging
	<b>Dimensions</b>	351 mm x 221 mm x 273 mm	458 mm x 222 mm x 152 mm
	<b>Barcode Reader Connection</b>	RS232	USB, Type B
	<b>USB Ports</b>	One free port	2 ports, including one for the barcode reader
	<b>Optional software</b>	DCSX: donation data management software. Store the donation sheets.	Hemolog 6 donation data management software. Store the donation sheets and curves
	<b>STANDARDS MET</b>		
	<b>Technical Standards</b>	IEC 60601-1	Same
		IEC 60601-2	Same

## SECTION 5 510 (K) Summary

### **Testing in Support of Substantial Equivalence Determination**

Testing according to ANSI AAMI 60601-1, IEC 60601-1-2 demonstrated that HemoMix 3 with DCSX software performs as intended. The predicate device has been tested according to the same standards.

### **Summary of Safety and Effectiveness**

All the necessary safety tests were performed and documented. The results demonstrate that the subject device complies with applicable international standards (ANSI AAMI 60601-1, IEC 60601-1-2, ISO 14971, IEC 62304, and IEC 62366-1) and it is safe as the predicate devices. All the necessary performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject device is effective and performs as well as the predicate devices. The minor differences between the devices do not raise any new issues of safety or efficacy.

### **Conclusion:**

The submitted and the predicate device have the same indications for use and technological characteristics. The test results and comparison results show that the proposed device is substantially equivalent to the predicate devices in performance.

Based on the intended use, technological characteristics, and performance testing, the proposed HemoMix 3 with DCSX software has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.