

## 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 Names :** HemoMix 4 (Basic version), HemoMix 4 (Internal optional RFID installed version)

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

### **Predicate device**

Predicate Device: HemoMix 3 with DCSX Software

510(k) Number: BK180229

510(k) Clearance Date: October 4, 2018

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 4 (Basic version) and HemoMix 4 (Internal optional RFID installed version) are automated blood monitors/mixers 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 4 (Basic version) and HemoMix 4 (Internal optional RFID installed version) are electronic automatic blood collection monitors/mixers used to perform whole blood collection from donor. HemoMix 4 (Basic version) and HemoMix 4 (Internal optional RFID installed version) mix 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 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).

HemoMix 4 (Basic version) and HemoMix 4 (Internal optional RFID installed version) are 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

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option mode) or store them in its memory. The collection parameters can be set locally on the device and / or can be programmed by an external application, named DelcoNet.

**Comparison of Technological Characteristics**

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

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**TABLE: Predicate Device Comparison**

<b>Model</b>	<b>HemoMix 4 (Basic version), HemoMix 4 (Internal optional RFID installed version) <u>Subject Device</u></b>	<b>HemoMix 3 with DCSX software BK180229</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>	<i>Topic of the pre-submission program</i>	510(k) Traditional
<b>510(k) Number</b>	NA	BK180229
<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>Where Used</b>	Fixed or mobile whole blood collection	Same
<b>Classification</b>	Device	Same
<b>Power Source</b>	100-240 Vac or rechargeable battery	115/230 Vac or rechargeable battery
<b>Power Supply</b>	Input: 24 Vdc (external power supply) (1)	Input: 115/230 Vac
<b>Barcode Reader</b>	Integrated (2)	External accessory
<b>Control Panel</b>	LCD display and touch panel (3)	LCD display and keyboard
<b>Transmission of Data</b>	Bidirectional, wireless or wired connection	Same
<b>Tube Holder</b>	Yes (4)	No
<b>Barcode Reader Holder</b>	No	No
<b>Optional software</b>	DelcoNet (5)	DCSX

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### **Justification of differences**

- (1) The power supply input is 24 Vdc but it is connected to an external 100-240 Vac medical power supply which is equivalent from functional and safety standpoint to internal ones.
- (2) The barcode reader is integrated in the device but it is functionally equivalent to the externally connected ones
- (3) The glass touch panel implements the same functionality of a membrane keyboard through a more flexible and reliable technology, improving the ergonomics of the user interface
- (4) The tube holder is an accessory used to position the blood tubes near the device during the blood collection. The tube holder is not necessary for the correct use of the device and it doesn't influence the performances of the device but improves the ergonomics for the operator
- (5) DelcoNet and DCSX software have similar features and performances. DelcoNet software will be submitted with an individual 510(K) application, before the HemoMix 4 application.

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

Testing according to ANSI AAMI 60601-1, IEC 60601-1-2 demonstrated that HemoMix 4 (Basic version) and HemoMix 4 (Internal optional RFID installed version) perform 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 4 with has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.