SECTION 5

510(K) SUMMARY

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Section 5 - 510(k) SUMMARY

SUMMARY PREPARATION DATE:

26 September 2016

5.1 OWNER'S PARTICULARS:

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5.3 DEVICE MANUFACTURER's PARTICULARS:

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5.4 DEVICE NAME:

Trade Name:	MacoMix HM20 and Hemolog 6
Product Code:	KSQ
Common Name:	Blood Mixer
Classification Name:	Blood Mixing and Blood Weighing Device
Regulation:	21 CFR 864.9195

5.5 PREDICATE DEVICE:

Biomixer BM330 with XBee (Wireless) Option. BK090010

5.6 DEVICE DESCRIPTION:

MacoMix HM20 and Hemolog 6 consist of two parts: The MacoMix HM20 device and optional Hemolog 6 software. The MacoMix HM20 is a mechanical mixer for blood bags used during whole blood collection. The device is able to mix collected whole blood from a donor and the anti-coagulant contained in the blood collection bag. The mechanical mixing is controlled by a motor, resulting in a gentle oscillation of the tray. Clamping and monitoring the blood collection are made due to a weight measurement system. The MacoMix HM20 automatically clamps the collection line at the volume manually programmed by the operator or volume calculated using the optional Hemolog 6. The objective is to have non-coagulated whole blood in the blood collection bag.

The MacoMix HM20 can be operated through the power supply or via a battery. It can be used either for fixed or for mobile whole blood collections.

The device is controlled through a sloping keyboard. A screen clearly displays the information and operations related to the whole blood collection.

A green light indicates normal operation and a red light as well as an audible and visual alarm indicate an anomaly during whole blood collection.

The device uses the mixing tray to hold the blood bags and ensure mixing of whole blood with the anticoagulant as well as measuring the weight of the blood bags. Measurements are displayed in milliliters (ml) taking into account the density of the blood as 1.06 gr / ml.

The whole blood mixer stops mixing and clamps the tubing at the target volume.
Each collection can be identified by one or more barcodes with systematic checks to ensure traceability.

The device can store the donation sheets and curves.

A donation sheet is the data gathered by the mixer before, during and after a whole blood collection. A curve is a volume/time graph of the whole blood collection from start to end. A memory area is dedicated to the storage of 210 donation sheets with joint graphs. The donation sheets can be retrieved on a PC via the optional Hemolog 6 software or by a USB FAT32 key.

A custom setting allows a quick adaptation to all procedures

5.7 INTENDED USE:

The MacoMix HM20 device and optional Hemolog 6 software system is an 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.

5.8 TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

Predicate Device:

Biomixer BM330 with XBee (Wireless) Option. BK090010

PREDICATE DEVICE COMPARISON:

Substantial Equivalence	Characteristic	Predicate Device: LJUNGBERG & KÖGEL AB Biomixer 330 with Xbee	MacoPharma MacoMix HM20
	General		
	System	Biomixer 330 and Optional Xbee Wireless Connection	MacoMix HM20 and optional Hemolog 6
	Purpose	To replace manual mixing of whole blood collection with automated mixing.	Same

Substantial Equivalence	Characteristic	Predicate Device: LJUNGBERG & KÖGEL AB Biomixer 330 with Xbee	MacoPharma MacoMix HM20
	Intended Use	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
	Where Used	Fixed or mobile whole blood collections	Same
	Classification	Device	Same
	Product Code	KSQ	Same
	Common Name	Blood Mixer	Same
	Regulation Number	21 CFR 864.9195	Same
	Power Source	100-240 Vac or Internal Rechargeable battery	Same
	Power Supply	Input: 100-240 Vac, Output: 24V	Same
	Battery	NiMh, 12/V	Same
	UL	UL Approved	Same
	Barcode Reader	Yes, removable	Same

Substantial Equivalence	Characteristic	Predicate Device: LJUNGBERG & KÖGEL AB Biomixer 330 with Xbee	MacoPharma MacoMix HM20
	Barcode Symbologies	1-D	Same
	Barcode Reading	ISBT 128	Same
	Instrument Status Information	In real-time	Same
	Access Control	User access limited to authorized clinical professionals with specific privileges. Every user is unique and has a user identifier and specific password. Complies with 21CFR11	Same
	Data Storage	Internal	Same
	Wireless Modem	Optional	Same
	Transmission of Data	Bidirectional, wireless or through direct connection	Same
	Useful Life	5+ years	Same
	Control Panel	LCD display, back lit	Same
	Blood Bag Suitability	All types	Same
	Automatic Tare	Yes	Same
	Automatic tube clamp , location	Yes, frontal	Same
	Standards Met		
	Technical Standards	IEC 60601-1	Same
		EN 60601-1-2	Same

Substantial Equivalence	Characteristic	Predicate Device: LJUNGBERG & KÖGEL AB Biomixer 330 with Xbee	MacoPharma MacoMix HM20
	Hardware		
	Peripherals	Tray scale and barcode reader	Same
	General		
	Battery Operating Time	12 hours	22 hours
	Internal Data Storage	Yes, up to 1000 collections	Yes, up to 210 collections
	Weight	3.7 kg without packaging	4.15 kg without packaging
	Tube Holders	No	Yes
	Barcode Reader Holder	No	Yes
	Hardware		
	Barcode Reader Connection	9-pole DSUB	USB, Type B
	USB Ports	One free port	2 including one for Barcode reader

5.9 DISCUSSION:

MacoProductions concludes that based on all the information submitted and discussed in this submission, MacoMix HM20 is substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the United States.

5.10 SAFETY AND EFFECTIVENESS DATA:

The MacoMix HM20 and optional Hemolog 6 were developed using established procedures. Unit tests and system tests were done by the Macopharma automation and software team. Completed systems are tested and validated using test scripts for defined scenarios and are included in appropriate sections.

Non Clinical System Testing:
The system was tested for validation and verification of functions based on risk analysis and good software lifecycle practices and the results passed predetermined acceptance criteria. No critical failures were detected and there are no unresolved anomalies.

Performance Testing:
Bench testing was conducted by the Macopharma automation team. A weight verification protocol was conducted using 2 collections on the MacoMix HM20 mixers with different target volumes at different flow rates during the process. The first with 460ml and the second with 480ml of water. Each collection was performed alternatively. On 1533 collections we obtained the following results:

	Calculated by the device	Calculated by the reweighing
Number of collection in tolerance range.	1526 **(99.54%)**	1533 **(100%)**
Number of collection out of tolerance range	7 **(0.46%)**	0 **(0%)**
Average of the precision	-2.01g **(-0.43%)**	-2.52g **(-0.54%)**
Standard deviation of the precision	2.54g **(0.54%)**	2.88g **(0.61%)**

No critical failures were detected.

Performance Testing – Clinical
In addition, installation, operational and performance qualification validation testing of three hundred ninety nine (399) MacoMix HM20 mixers was conducted at 3 clinical sites, the Suncoast

Blood Bank, Sarasota, FL, the Mississippi Valley Regional Blood Center, Davenport, IA and the Shepeard Community Blood Center, Augusta, GA. The MacoMix System will be considered to be acceptable if donor units collected on mixers, after IQ/OQ/PQ, meet the acceptable criteria of within +/-10 mL or +/-2% from target collection volume. The validation performed as expected and all three hundred ninety nine (399) mixers passed the validation protocol with no issues.

5.11 CONCLUSION:

Based on the above comparison of the MacoMix HM20 and optional Hemolog 6 to the predicate device, the MacoMix HM20 and optional Hemolog 6 are substantially equivalent to the predicate device. The results of testing demonstrate that the system has met the expectation of high product quality and is safe and effective for its intended use.