

510(K) SUMMARY

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Date the summary prepared: June 30, 2017

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DEVICE NAME:

Trade Name: MacoPress Smart and DMS Plus
Common Name: Blood Component Separator
Classification Name: Blood Bank Supplies

PREDICATE DEVICE:

CompoMat G5 and CompoMaster Net G5 System. BK 110012

DEVICE DESCRIPTION:

The MacoPress Smart (MPS) and DMS Plus consist of two parts: the MacoPress device and the DMS Plus management software. The MacoPress Smart functions as an automated press, clamp, and sealer to separate the blood components from the centrifuged blood bag systems. By means of the controlled movement of a press used to press the bag of centrifuged whole blood, a network of clamps fitted with sealer heads, three or more weighing scales (depends by the chosen configuration) and a series of optical sensors, MPS automatically and accurately extracts and transfers blood components from the main bag to the satellite bags. With the use of the DMS Plus software, the separation procedures can be programmed to collect data of manufacturer components that can then be recorded, stored and analyzed.

INTENDED USE:

The MacoPress Smart (MPS) and DMS Plus consist of two parts: the MacoPress Smart device and the DMS Plus Management software. The MacoPress Smart is intended as an automated blood component separator used for blood component separation and preparation. With the use of the DMS Plus software, the separation procedures can be programmed to collect data of manufacturer components that can then be recorded, stored and analyzed.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

Predicate Device

CompoMat G5 and CompoMaster Net G5 System. BK 110012:

Substantial Equivalence	Characteristic	Predicate Device: CompoMat G5 and CompoMaster Net G5 System. <u>BK 110012</u>	MacoPress Smart and DMS Plus
SIMILARITIES	GENERAL		
	System	Consists of 2 parts – A hardware device and a management software	Same
	Purpose	The System is designed to replace the manual press traditionally used	Same
	Intended Use	Separate blood components from the centrifuged blood bag systems.	Same
	Where Used	Blood Component Manufacturers	Same
	Classification	Blood Bank Supplies	Same
	Product Code	KSS	Same
	Common Name	Blood Component Separator	Same
	Regulation Number	21 CFR 864.9050	Same
	Power Supply	100 - 240 V, 50 - 60 Hz	Same
	UL	UL Approved	Same
	Removal of air bubble and weighing of air bag in one step	Maximizes efficiency and plasma yield by automated air removal and weighing of plasma bags in a single step	Same
	Plasma loss during removal process	Avoids plasma loss during removal process	Same



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Substantial Equivalence	Characteristic	Predicate Device: CompoMat G5 and CompoMaster Net G5 System. BK 110012	MacoPress Smart and DMS Plus
	Barcode Symbologies	1-D barcode	Same
	Barcode Reading	ISBT128	Same
	Reading	Automated	Same
	Interface	Interfaced with Laboratory Information System	Same
	Instrument status information	In real-time	Same
	Access control	User access limited to authorized individuals with specific privileges. Every user is unique and has a user identifier and specific password. Complies with 21CFR11.	Same
	Automatic documentation of separation	In real-time	Same
	Main press movement	Processor controlled electronic stepper motor	Same
	Hematocrit level adjustment	8 optical sensors in the front press plate	Same
	End weight adjustment	Front press plate distance	Same
	Fixation bag front press	2 x Suspension pins	Same
	Fixation plasma bag lateral press	1x fork holder	Same
	Useful life	5-10 years	Same
	Cleaning clamps	Removable caps	Same
	Optional external scale	1 x external scale	Same
	Process time T&T	1:30 – 2:30 min	Same
	Control panel	6 x function key's	Same
	Tube detection in clamps	yes	Same

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Substantial Equivalence	Characteristic	Predicate Device: CompoMat G5 and CompoMaster Net G5 System. BK 110012	MacoPress Smart and DMS Plus
HARDWARE			
	Server Platform	Windows 2008	Same
	Client Platform	Windows XP/Vista/7/8	Same
	Client Terminal	PCs	Same
	Minimum CPU	Intel compatible Min 1.5GHZ	Same
	Minimum Hard Disc	20 Gig Minimum	Same
	Minimum RAM	1.5 Gig	Same
	Monitor	min. 1024 x 768 resolution (xGA), 17" Monitor recommended	Same
	CD/DVD	Required	Same
	USB Port	One free port (USB2.0)	Same
	Barcode Devices	Bar-code scanners and readers	Same
	Peripherals	External tray scale, External sealer handgun, Thermal printer.	Same
	Networking	Standard computer networks using TCPIP.	Same
	LAN / WAN	Ethernet cables, Routers, Switches, Hubs	Same
	Wireless Devices	MiFi and Access Points	Same
SOFTWARE			
	Interface	ASCII formatted data can be interfaced to host computer system	Same
	Programming Language	Microsoft Dot Net	Same
	Database	MS SQL	SQL Lite

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Substantial Equivalence	Characteristic	Predicate Device: CompoMat G5 and CompoMaster Net G5 System. BK 110012	MacoPress Smart and DMS Plus	
DIFFERENCES	GENERAL			
	Weight	30 kg without packing	35 kg without packing	
	Sealing tube at the end of separation	6 x clamps with sealing function	5 x clamps with sealing function	
	Optical sensors	6	2	
	Control panel	Color display	Monochrome display	
	Lateral plasma press for air removal	Powered by spring force	Powered by electronic stepper motor	
	Cannula opener system	Compo flow Closed system only for compo flow cannula	REVO Open system for all type of STD cannula	
	Integrates scales	3 x scales	5 x scales	
	Tube position indicator	Display	Clamps display	
	Red cell + additive solution mixer	no	Yes	
	Door front press	electrical motor	manual	
	Quick pressure release function in case of leaked tube or bag	No Menu section with separation stop bottom	Yes Door release arm	
	HARDWARE			
	Ethernet connects	up to 100 devices	Up to 256	
	External sealing handle	0	1	
	SOFTWARE			
	Database	Not available	SQL Lite	
	Programing Language	Not available	C++, Python	

Table 5-1 Predicate Device Comparison

DISCUSSION:

MacoProductions concludes that based on all the information submitted and discussed in this submission, MacoPress Smart (MPS) and DMS Plus 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.

SAFETY AND EFFECTIVENESS DATA:

The MacoPress Smart (MPS) and DMS Plus was developed using established procedure for software development. Unit tests and systems tests were done by our software team. Completed systems are tested and validated using test scripts for defined scenarios and included in appropriate sections.

Beta Testing and Performance Testing – User Acceptance Testing:

Beta Testing was done in a blood bank user environment, OneBlood, Inc., Orlando, Florida. The results passed predetermined acceptance criteria and are contained in Section 18b of this 510(k) Notification. No critical failures were detected and there were no unresolved anomalies.

Clinical System Testing – User System Testing:

The system was tested in a blood bank user environment, OneBlood, Inc., Orlando, Florida. The results passed predetermined acceptance criteria and are contained in Section 20b of this 510(k) Notification. No critical failures were detected.

Non Clinical System Testing:

The system was tested for validation and verification of functions and the results are contained in Section 20c of this 510(k) Notification. No critical failures were detected.

CONCLUSION:

Based on the above comparison of the MacoPress Smart (MPS) and DMS Plus to the predicate device, the MacoPress Smart (MPS) and DMS Plus is substantially equivalent to the predicate. 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.