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510(k) SUMMARY

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Modified Device

Trade Name:	CompoMat G5 *Plus* and CompoMaster Net G5 *Plus* System
Common or Usual Name:	Blood Component Separator
Product Code:	KSS
Classification Regulation:	21 CFR § 864.9050
Classification Name:	Blood Bank Supplies
Review Panel:	Hematology
Device Class:	Class I

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed

Trade Name:	CompoMat G5 and CompoMaster Net G5 System
Common or Usual Name:	Blood Component Separator
Product Code:	KSS
510(k) Number:	BK110012
Date Cleared:	August 2, 2012
Device Class:	Class I

Device Description

The CompoMat G5 *Plus* and CompoMaster Net G5 *Plus* System consists of two parts: the CompoMat G5 *Plus* device and CompoMaster Net G5 *Plus* data management software.

The CompoMat G5 *Plus* functions as an automated press, clamp and sealer to separate the blood components after centrifugation in a blood bag system. With the use of the CompoMaster Net G5 *Plus* software, which is installed by the user on commercially available computer hardware, the separation procedures can be programmed and manufacturer data of components can be recorded and stored.

Indications for Use

The CompoMat G5 *Plus* and CompoMaster Net G5 *Plus* System is intended as an automated blood component separator used for blood component separation and preparation.

Technological Characteristics as Compared to the Predicate Device

The System is designed to replace the manual press traditionally used. The main design and functional components remain the same as the predicate device. Some improvements, such as the application of automatic cannula breakers, wider RBC scale and improved A-detector sensitivity were implemented in the CompoMat G5 *Plus* and CompoMaster Net G5 *Plus* system.

Performance Data

The ability of the CompoMat G5 *Plus* to support the automated separation of whole blood into components was evaluated and compared to the results obtained with the currently available commercial model, the CompoMat G5. No major differences were found with regard to the preparation procedure or results for the red blood cells (RBC), platelets (PLT) and plasma (PLS) products. Results passed the acceptance criteria.

The system also completed appropriate testing to support electrical safety and electromagnetic compatibility. Full system verification testing confirmed the changes did not impact other functional areas of the device.

Conclusion

The verification and validation testing demonstrate that the modified CompoMat G5 *Plus* device is substantially equivalent to the predicate device.