

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

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DEVICE IDENTIFICATION

Device Trade Name: CompoMat G5 and CompoMaster NET G5 System

Common Name: Blood component separator

Classification Name: KSS (21 CFR 864.9050)

SUBSTANTIAL EQUIVALENCE The device is substantially equivalent to the currently marketed Compomat G4 and Compomaster NT System (BK030022).

DEVICE DESCRIPTION

The CompoMat G5 and CompoMaster Net G5 System consist of two parts: the CompoMat G5 device and the CompoMaster Net G5 management software.

The CompoMat G5 functions as an automated press, clamp, and sealer to separate the blood components from the centrifuged blood bag systems. With the use of the CompoMaster Net G5, the separation procedures can be programmed and manufacturer data of components can be recorded and stored.

INTENDED USE

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

TECHNOLOGICAL CHARACTERISTICS

The System is designed to replace the manual press traditionally used. The main design and functional components remain the same as the predicate device (Compomat G4 and Compomaster NT System). Some improvements (software, electrical compressor, sensor control, etc.) were implemented in the CompoMat G5 and CompoMaster Net G5 System.

The testing data and software documentation (verified and validated) show that the new characteristics do not affect safety and effectiveness of the device.

PERFORMANCE DATA

The ability of the CompoMat G5, to support the automated separation of the whole blood into components, was evaluated and compared to the results obtained with the currently available commercial model, the Compomat G4 (BK 030022). No major differences between the CompoMat G5 and the Compomat G4 were found with regard to the preparation procedure or results for the RCC (red cell concentrate), PLT (platelets), and PLS (plasma) products.

The system also completed appropriate testing to support electrical safety, electromagnetic compatibility, and wireless connectivity.

CONCLUSIONS

Based on the information submitted, it is concluded that the CompoMat G5 and CompoMaster Net G5 System is suitable for the separation of centrifuged whole blood into blood components, and substantially equivalent to the predicate Compomat G4 and Compomaster NT system.