



MACOPRODUCTIONS S.A.S.

510(k) SUMMARY

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DEVICE MANUFACTURER'S INFORMATION:

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DEVICE IDENTIFICATION:

Device Trade Name: MacoPress Smart Smarter and DMS Plus
Common Name: Blood Component Separator
Classification Name: KSS (21 CFR 864.9050, Blood Bank Supplies)
Device Classification: Class II
Review Panel: Hematology

**SUBSTANTIAL
EQUIVALENCE:**

The MacoPress Smart Smarter and DMS Plus is substantially equivalent to the currently marketed MacoPress Smart (MPS) and DMS Plus (BK170085).

DEVICE DESCRIPTION:

The MacoPress Smart Smarter and DMS Plus consist of two parts: the MacoPress Smart Smarter device and the DMS Plus management software.

The MacoPress Smart Smarter 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 Smarter and DMS Plus 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, operating principle and indicated use remain similar to the predicate device (The MacoPress Smart (MPS) and DMS Plus (BK170085)). The main modifications implemented with the MacoPress Smart Smarter include: additional optical sensors, touch screen control panel and tube position indicators.

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

PERFORMANCE DATA:

Performance validation was performed to support the automated separation of the whole blood into components and compared to the results obtained with the currently cleared device, MacoPress Smart (MPS) (BK170085). No major significant differences were found between the MacoPress Smart (MPS) and the MacoPress Smart Smarter with regard to the preparation procedure or results for the red cells, platelets and plasma products.

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

CONCLUSION:

Based on the information described in this submission, it is concluded that the MacoPress Smart Smarter and DMS Plus management software is suitable for the separation of centrifuged whole blood into blood components and is substantially equivalent to the predicate MacoPress Smart (MPS) and DMS Plus.