

510(k) Giotto Monza 510(k) Summary

The purpose of this 510(k)-summary document is to provide an understanding of the basis for a determination of substantial equivalence according to 21 CFR 807.92 content and format prescriptions.

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Device Name	
Application Number	BK 231039
Device Trade Name	Giotto Monza
Common Name	Blood Component Separator
Classification Name	Supplies, Blood Bank
Regulation Number	864.9050
Product Code(s)	KSS

Legally Marketed Predicate Device	
510(k) Number	BK 180306
Device Trade Name	Macopress Smart Smarter
Common Name	Blood Component Separator
Classification Name	Supplies, Blood Bank
Regulation Number	864.9050
Product Code(s)	KSS

Device Description Summary

The Giotto Monza is an automated blood component separator. The device is designed to replace the manual press, traditionally used to extract blood components from centrifuged whole blood, with a motorized press and clamps controlled by a microprocessor. Giotto Monza automatically and accurately extracts and transfers blood components from the main bag to the satellite bags by means of the controlled movement of its press (main press), used to squeeze the bag of centrifuged whole blood, a network of clamps fitted with sealing heads, used to control the flow

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in the satellite bags, four scales, used to weight the blood components, and a series of optical sensors, used to detect the components position.

Device Intended Use

The Giotto Monza is intended as an automated blood component separator used for blood components separation and preparation.

The Giotto Monza device has the same indication for use of the Macopress Smart Smarter predicate device. They share the same system architecture and technology and are based on the same operation principles in order to squeeze the centrifuged whole blood bag and extract in an automated way the blood component in satellite bags.

Subject and Predicate Device Technological Comparison

The Giotto Monza device is derived from the Macopress Smart Smarter device and consequently it shares with the predicate device the indication for use, the technology, the system architecture, the principle of operation and the functional diagram.

Here is a summary of the technology main items comparison between subject and predicate device (extract from the Substantial Equivalence discussion file attached to eSTAR file):

Model	Macopress Smart Smarter Predicate Device	Giotto Monza Subject Device
Principle of Operation	Processor based electronic device with motorized press for automated blood cells separation	Same
Device architecture	Based on a control board managing touch screen (user interface) and communication and a cpu board controlling press, clamps, sensors and separation process	Same
Electronics	Microprocessor based electronic boards, power supply, sensors motors and cables	Same
Power Source	Mains powered	Same
Power Supply	100 - 240 VAV, 50 – 60 Hz	Same
Battery	No	Same
Control panel (display & keyboard)	4.3" color graphic LCD with touch screen	Same
Front press	Moved by processor controlled electronic stepper motor	Same
Front press door	Aluminum door white painted	Aluminum door nickel color painted (2)
Front press sensor	Optical. 12 x LED sensors	Optical. 10 x LED sensors (1)
Lateral plasma press for air removal	Moved by processor controlled electronic stepper motor	Same

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<i>Model</i>	<i>MacoPress Smart Smarter Predicate Device</i>	<i>Giotto Monza Subject Device</i>
Bag fixation on lateral press	1x fork holder	2x suspension pins (3)
Tube clamps	5x tube clamps	Same
Tube detection	Correct tube positioning optical sensors in all clamps	Same
Tube position indicator	Red/green LED in all clamps	Same
Body shells	Polyurethane. White cover and front panel, BLUE lateral panels	Polyurethane. White cover and front panel, RED lateral panels (2)
Mechanical structure and other parts	Mechanical parts are steel or aluminum made including frame, press plates, press door, movement parts.	Same
Integrated scales	4 x scales	Same
Scales weighting accuracy	0÷300 g accuracy ± 3 g (0÷0,66 lbs accuracy $\pm 0,007$ lbs) 351g- full scale $\leq \pm 1\%$ (0,77 lbs full scale $\leq \pm 1\%$)	Same
Separation process time T&T	45" to 2'30" average extraction duration	Same
Sealing tube at the end of separation	5 x clamps with RF sealing function	Same
User Interface	Colored touch icons on white background style	White touch icons with colored marks on black background style (2)
Blood Bags Suitability	All blood bags	Same
USB Ports	1 USB port (USB2.0) available to user	Same
LAN Modem	Integrated Ethernet modem, up to 256 devices	Same
Wireless Modem	Predisposed to external USB Wi-Fi adapter	Same
Data Storage	Up to 100 programs and more than 1000 separation results	Same
Transmission of Data	Stored data transmitted to external software if connected	Same
Service Life	10 years	Same
Dimensions	325W x 422D x 420H mm (12,8W x 16,6D x 16,5H inches)	Same
Weight	38 Kg without packaging	Same
Standards Compliance	Safety: IEC 60601-1 EMC: IEC 60601-1-2 IEC 61010	Same
RFID read/write	Integrated as optional	Same

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The relevant changes implemented in Giotto Monza respect the Macopress Smarter predicate device are limited to:

- 1) The front press optical sensor is featuring 10 levels (LEDs) instead of 12, with the same separation accuracy and reliability in components separation (same optical diodes, electronics and control algorithm) and a subset of the programming options. Widely discussed through additional testing and information requested.
- 2) Aesthetic differences in user experience style (black background for Giotto Monza) and in some external parts: plastic shell color, metallic parts color.
- 3) The fixation of plasma bag on lateral has a different shape: 2 pins for Giotto Monza vs fork holder for Macopress. Minor detail: different solutions for the same purpose and effectiveness.

Non-Clinical Tests Summary and Conclusions

Two documents have been provided, through an amendment to the eSTAR submission file, to support the determination of the substantial equivalence:

- 1) The analysis of the substantial equivalence of OPT2 optical sensors, following an additional data request included in a Technical Screening Hold letter.
- 2) The report of a study finalized to determine if the blood component separators, Giotto Monza and MacoPress Smarter, are substantially equivalent in terms of blood components processing (GIOMZ_FITPR_Rev.1.2). This following an Additional Information Requested letter.

The technical analysis evidenced the accuracy equivalence between the two OPT2 optical sensors, in addition to the consideration that the predicated and subject devices are based on the same hardware and software architecture.

Regarding the primary end point of the study, the difference calculated among the mean values obtained on the two devices regarding the blood components recovery yield and purity has been successfully verified within the 10% admitted deviation. Therefore, no adverse events, such as discomfort or inconvenient hypotension or any reaction, and no device malfunctions, alarms, or operational issues have been evidenced during and after the procedure.

All the necessary safety tests were performed and documented. The results demonstrate that the subject device complies with applicable international standards and it is safe as the predicate devices. All the necessary performance tests in support of substantial equivalence determination were conducted. The tests demonstrate that the subject device is effective and performs as well as the predicate devices. The minor differences between the devices do not raise any new issues of safety or efficacy.

Conclusion

The submitted and the predicate device have the same indications for use and technological characteristics. The test results and comparison results show that the proposed device is substantially equivalent to the predicate devices in performance. Consequently, the proposed Giotto Monza device is considered to be substantially equivalent to the predicate device.

Date: March 12, 2025