510(k) Summary*

Sepax Cell Separation System and single use kits

510k owner: Biosafe SA
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Product:
- Trade name: Sepax Cell Separation System and single use kits
- Common name: Sepax 2 system
- Classification name: Cord blood processing system and storage container
- Classification: class II - special controls

Predicate device:
Sepax Cell Separation System and single use kits cleared as bk060036

Device Description:

The Sepax system consists of:
- The Sepax Main Unit (S-100): provides centrifugal and axial displacement drive to the chamber on the single-use separation kit, as well as drive to the directional valves. The main unit can be equipped with application specific Sepax software protocols.
- The Single-use kit (CS-xxx.x): contains the blood in a sterile environment during the complete operation – valves control the flow of blood components to the correct bag.

The Sepax 2 is the modified version of the Sepax main processing unit. The Sepax 2 is an evolution of the legally marketed (unmodified) Sepax. There is no change in its intended use and in its fundamental scientific technology.

Intended Use:
The Sepax system is a cord blood cell processing system intended for laboratory use in exclusive combination with a compatible single-use separation kit supplied by Biosafe. The cord blood to be processed has been previously collected and transported to the laboratory by other means.
The Sepax system allows the fast, automated and reproducible separation of cord blood. The Sepax system is not intended for use in transfusion applications at bedside, where blood circulates directly between a patient and the Sepax unit.

*As described in 21 CFR 807.92

Technological Characteristics:
The Notification of modification under the present 510(k) concerns the Sepax main processing unit S-100. The table below indicates the similarities and differences between the modified Sepax and its predicate device.

	Sepax	**Sepax 2**
Clearance	Cleared under 510(k) bk060036	Notification of modification under the present 510(k)
General		
Intended use / Indication for use	See Intended use Statement	Same
Fundamental scientific technology	The machine in conjunction with a sterile single use kit is used for cord blood cell separation. Rotational drive is provided by the electric motor, while piston displacement is assured by compressed air fed through a sterile filter of the chamber.	Same
Labelling	Operator manual describes the procedures steps and the machine use.	The operator manual has been revised to include the new user interface.
Device		
External design	Original design	Modification: Modernized housing shape
User Interface	Two lines LCD display	Modification: A touch-screen color display
Electronics system	Obsolete technologies for electronics	Modification: Recent technologies for electronics
Operating system	Windows DOS	Windows XP embedded
Software	Managing software called MAP Level of concern : Moderate	Modification: Managing software called GMAP Level of concern : Moderate
Core technology	1- Electrical motor for centrifugation 2- Pneumatic circuitry for piston drive Both compatible with single use kits	Same

Safety and Performance:
The Sepax 2 device conforms to applicable standard including medical device electrical safety standard IEC 60601-1. The design control activities have been performed to ensure that the safety and performance are substantially equivalent to the predicate device.

Conclusion:
It is the conclusion of Biosafe that the Sepax 2 system is substantially equivalent to and as safe and effective as the predicate device.

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