

March 26, 2026

510(k) Summary

Contact Details

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Device Name

Device Trade Name	Plasmacell-C Disposable Set
Common Name	Automated blood cell separator
Classification Name	Separator, Automated, Blood Cell, Diagnostic
Regulation Number	864.9245
Product Code	GKT

Legally Marketed Predicate Devices

Predicate 510(k) Number	BK110072
Predicate Trade Name	Plasmacell-C Disposable Set
Product Code	GKT

Device Description Summary

The Plasmacell-C Disposable Set is a self-contained processing system intended for the collection of plasma by membrane filtration. Collected plasma can be used as Source Plasma. The disposable set consists of a separation device, a reservoir, tubing set and connectors. The disposable set is sterilized by radiation to achieve a sterile fluid path.

The Plasmacell-C Disposable Sets are used with Autopheresis-C and Aurora Plasmapheresis systems to achieve a rapid separation of whole blood into concentrated cellular components and plasma by means of spinning membrane filter. The concentrated cellular components are returned to the donor, and the collected plasma can be processed as Source Plasma.

Intended Use/Indications for Use

The Plasmacell-C Disposable Set is intended for collection of plasma by membrane filtration.

Indications for Use Comparison

The indications for use of the Plasmacell-C Disposable Set is the same as the predicate device.

Technological Comparison

The modified Plasmacell-C Disposable Set has the same performance characteristics, the same components as the predicate device. The changes described in this application did not affect the fundamental scientific technology or principle of operation of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The proposed product modifications have been evaluated in accordance with the test methods specified in ISO 10993-1:2018. Functional testing was conducted in alignment with the established product design requirements. The results of these assessments confirmed that the proposed changes do not adversely affect the product's safety or effectiveness.

Clinical testing is not applicable.

The results of all verification activities demonstrated that the modified Plasmacell-C Disposable Set is substantially equivalent to the predicate device.