

February 19, 2025

510(K) SUMMARY

Contact Details

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Device Name

Device Trade Name	Adaptive Nomogram Bottle
Common Name	Plasma Pooling Bottle, Plasma Bottle, Pooling Bottle
Classification Name	Container, Empty, For Collection & Processing of Blood & Blood Components
Regulation Number	864.9100
Product Code	KSR

Legally Marketed Predicate Devices

Predicate 510(k) Number	BK190362
Predicate Trade Name	Plasmalink Bottle with Locking Luer Adapter
Product Code	KSR

Device Description Summary

Plasma bottles are empty, semi rigid, single use, non-pyrogenic and sterile fluid path collection bottles intended for the collection, storage and shipment of source plasma prior to fractionation. Plasma bottles are utilized in conjunction with applicable disposable sets and applicable plasmapheresis systems.

Intended Use/Indications for Use

For the collection, storage, and shipment of plasma prior to fractionation.

Indications for Use Comparison

The intended use/indications for use of the Adaptive Nomogram Bottle is the same as the predicate device.

Technological Comparison

The Adaptive Nomogram Bottle has the same performance characteristics, the same components, and the same materials as the predicate devices. 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 performance of the Adaptive Nomogram Bottle was verified by the same methods used in the previously cleared submission and passed the acceptance criteria. The intended use, fundamental scientific technology, safety and effectiveness of the proposed device remain unchanged from the predicate device. Based on the verification activities performed, the Adaptive Nomogram Bottle is substantially equivalent to the predicate device.