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510(K) SUMMARY

Date Prepared:

May 22, 2019

510(k) Owner and Contact Person:

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Device Regulatory Information:

Device Trade Name: Plasmalink Bottle with Locking Luer Adapter

Common Name/Usual Name: Plasma Pooling Bottle

Classification Name: 21 CFR 864.9100- Empty container for the collection and processing of blood and blood components

The empty container for the collection and processing of blood and blood components has been classified by the Center for Biologics Evaluation and Research as Class II device (45 FR 60638, Final Rule, Sept. 12, 1980).

Product Code and Classification Panel:

81 KSR (Hematology Panel) – Empty container for the collection and processing of blood and blood components

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fresenius Kabi is claiming substantial equivalence with the Plasmalink cleared under 510(k) #BK180293 on December 21, 2018.

Device Description:

The Plasmalink Bottle with Locking Luer Adapter is an empty, semi-rigid, single use, sterile nonpyrogenic fluid path collection container intended for the collection, storage and shipment of plasma prior to fractionation.

The Plasmalink Bottle with Locking Luer Adapter is utilized in conjunction with disposable sets and the applicable Plasmapheresis instruments.

Modification to the Existing Device:

This application is being submitted to address material changes in the existing Plasmalink Bottle with Locking Luer Adapter.

Statement of Intended Use/Indications for Use:

The Plasma Pooling Bottle is used for the collection, storage, and shipment of plasma prior to fractionation.

Technological Characteristics as Compared to the Predicate Device**Performance Data:**

The technological characteristics of the Plasmalink Bottle with Locking Luer Adapter remain the same as the predicate Plasmalink product cleared under 510(k) #BK180293.

The proposed device and predicate device have the same performance characteristics and intended use. The change in materials do not in any way change the fundamental scientific technology or principle of operation of the device.

Conclusion:

The fundamental scientific technology, intended use, safety and effectiveness of the Plasmalink Bottle with Locking Luer Adapter remain unchanged. The verification activities performed in support of the material changes described in this application provide evidence that the proposed device is substantially equivalent to the currently marketed Plasmalink Bottle.