Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

510(K) SUMMARY

Date Prepared:

November 30, 2018

510(k) Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9027285 Fresenius Kabi AG Bad Homburg, GERMANY 61346
Contact Name: **Title:** **Address:** **Telephone:** **Fax:** **E-mail:**	Betsy Brown Manager, Regulatory Affairs Fresenius Kabi USA, LLC Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-2573 847-550-2960 betsy.brown@fresenius-kabi.com
Official Correspondent: **Title:** **Address:** **Telephone:** **Fax:** **E-mail:**	Cheryl Roscher Vice President, Regulatory Affairs Fresenius Kabi USA, LLC Three Corporate Drive, 2nd Floor Lake Zurich, IL 60047 USA 847-550-7909 847-550-2960 cheryl.roscher@fresenius-kabi.com

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) #BK080033 on August 22, 2008.

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) #BK080033. 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 supplier of the changes described in this application provide evidence that the proposed device is substantially equivalent to the currently marketed Plasmalink Bottle.