5. 510(K) SUMMARY

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Owner and Contact Person:

Name:	Sharyn Orton, PhD
Title:	Director, Regulatory Affairs
	Fenwal, Inc.
Address (street):	Three Corporate Drive
	2nd Floor
Address (City, State, Zip Code):	Lake Zurich, IL 60047
Telephone:	(847) 550-7908
Fax:	(847) 550-2960
E-mail:	sharyn.orton@fenwalinc.com
Owner/Operator Number	**9098803**

Device Name(s):

(4R2065) Plasma Pooling Bottle and Transfer Set with Needle Adapter

(4R2067) Plasmalink Pooling Bottle with Luer Adapter

(4R2068) Plasmalink Pooling Bottle with Effluent Adapter

(4R2069) Plasmalink Bottle with Locking Luer Adapter

(R4R2069) Plasmalink Bottle with Locking Luer Adapter

(R4R2070) Plasmalink Bottle with Effluent Adapter

Common Name:

Plasma Pooling Bottle

Classification Name:

Empty Container for the Collection and Processing of Blood and Blood Components (21 CFR 894.9100)

Legally Marketed Device:

PLASMA-GARD® Plasma Pooling Bottle with Integral Transfer Set (BK 830009)

Device Description

The Plasma Pooling Bottle (code 4R2987) was originally cleared for market entry by the Center for Biologics Evaluation and Research under 510(k) BK 830009 on January 25, 1984. The product described in 510(k) BK 830009 consists of a 1000 mL blow molded high-density polyethylene (HDPE) bottle with a specially designed cap assembly, integral vent and pre-attached transfer set. Through the design control process, the Plasma Pooling Bottle has been modified over time, and is now called the Plasmalink Bottle.

The design for the Plasmalink Bottle consists of an HDPE bottle, an ABS connector, a plasma line with PVC tubing and needle adapter connector and a vent line with PVC tubing and microbial filter. Products that are CE Marked will also contain a tamper evident band. Previous changes to the original design were assessed and classified as minor; the intended use of the product was not altered. However, these changes did result in new product codes marketed in either the US or Europe.

The Plasma Pooling Bottles have been classified by the Hematology and Pathology Devices Section of the Medical Device Panel as Class II in 21 CFR 864.9100 under the classification of “Empty container for the collection and processing of blood and blood components.”

Statement of Intended Use

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

Technological Characteristics

Fenwal Plasma Pooling Bottles are designed for the collection, storage, and shipment of plasma prior to fractionation. There are two design types; bottles made with the Luer Adapter and those made with the Effluent Adapter. There are three product codes manufactured with the latest modified bottle design: 4R2069, R4R2069, and R4R2070. The modified bottle design eliminates the current heat seal operation and replaces it with a mechanical gasket seal. A protective cap, which is snapped shut following plasma collection, is designed to protect tubing leads during the fractionation process. The bottom and shoulder of the bottle have been modified to improve stiffness and resistance to impact. The plasma and vent lines for all product codes with the latest design have been changed to a stiffer material to help reduce kinking. The plasma line for product codes 4R2069 and R4R2069 have been reconfigured to include a locking luer connector for use with Fenwal disposable sets. Product code R4R2070 includes an effluent adapter, in place of the locking luer, for use with the Haemonetics disposable sets to allow for customer flexibility.

Product codes R4R2069 and R4R2070 include the following additional features required for CE Marking: 1) tamper band on the plasma line connector and cap, 2) language translations for countries in which the bottle will be sold as defined by marketing and 3) use of EN 980 symbols for labeling.

In summary:

4R2065 with interlink added → 4R2067

4R2067 with Haemonetics connector added → 4R2068

4R2068 with a new bottle design → 4R2069

4R2069 with tamper evidence, labeling for CE marking, and new bottle design → R4R2069 (new product code)

4R2068/4R2069 combined design, tamper evidence, labeling for CE marking → R4R2070 (new product code)

Conclusion

The original device (4R2987) listed in this summary have been cleared for Travenol Laboratories under 510(k) number BK 830009, which showed the product to be safe and effective. Subsequent products have been created following design control. A comprehensive assessment of the modifications and product codes created, indicated that no 510(k) submission was required. Fenwal is submitting this 510(k) notification to update the product history with the modifications made and to obtain clearance for revised labeling to include the new product codes (R4R2069 and R4R2070), language translations for countries in which the bottle will be sold, the use of symbols and CE Marking. Section A5 of the guidance document, Deciding When to Submit a 510(k) for a Change to an Existing Device indicates revisions to labeling that are not added for clarity or to insure safer or more effective use, requires the submission of a 510(k).

The fundamental scientific technology, intended use, safety, and effectiveness are the same as the originally cleared device (4R2987). The Plasma Pooling Bottle is still used for the collection, storage, and shipment of plasma prior to fractionation. A risk assessment has been conducted (**See Section 21**) and changes made to the device, conforms to design control requirements. Verification and validation activities demonstrate that the design outputs of the modified device meet the design input requirements. (**See Section 18**) This notification is being submitted as a Special 510(k) based on the New 510(k) Paradigm, which indicates once the manufacturer has ensured satisfactory completion of the above processes, a “Special 510(k): Device Modification” may be submitted.