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510(k) SUMMARY

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Device Trade Name

Fenwal Plasmalink Transfer Pack Container with Luer Adapter and No Outlet Ports

Other Marketing Names

Fenwal Plasmalink Transfer Pack Container
Fenwal Plasmalink Transfer Pack
Plasmalink Transfer Packs

Common Name/Usual Name

Transfer Packs

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 under the Code of Federal Regulations (CFR) as a Class II device (45 FR 60638, Final Rule, Sept. 12, 1980).

Product Code and Classification Panel

KSR, Hematology Panel

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed

Fresenius Kabi Transfer Packs were on the market prior to May 28, 1976 (then branded Fenwal) and are therefore pre-amendment devices.

Fresenius Kabi is claiming substantial equivalence to the current version of the Plasmalink Transfer Pack Product Code 4R2088P (predicate device).

Device Description

The proposed Fenwal Plasmalink Transfer Pack with Luer Adapter and No Outlet Ports (Product Code 4R2088P) is an empty, flexible, single use, sterile, nonpyrogenic fluid path, plastic collection container intended for processing and/or storage of blood or blood components. This specific code is generally used for the collection and storage of plasma prior to fractionation. The Plasmalink Transfer Pack consists of 1000mL DEHP PVC plastic bag and bag port, a sampling Y-site, a male luer adapter and luer cap, and a connection tubing.

Statement of Intended Use/Indications for Use

Transfer Packs are intended for processing and/or storage of blood or blood components.

Technological Comparison as Compared to the Predicate Device

The technological characteristics of the Fenwal Plasmalink Transfer Pack Container with Luer Adapter and No Outlet Ports remain the same as the predicate device. The proposed device and predicate device have the same performance characteristics and intended use. The change in container material does not in any way change the fundamental scientific technology or principle of operation of the device.

Modification to the Existing Device

This application is being submitted to address material changes in the existing Plasmalink Transfer Pack. There are no other changes.

Performance Data

The performance of the proposed Fenwal Plasmalink Transfer Pack Container with Luer Adapter and No Outlet Ports was tested by material qualification studies, shelf life studies, functional tests, and in vitro clinical studies.

Results passed the acceptance criteria.

Conclusion

The fundamental scientific technology, intended use, safety and effectiveness of the Fenwal Plasmalink Transfer Pack Container with Luer Adapter and No Outlet Ports remain unchanged. The verification activities performed in support of the changes described in this application provide evidence that the proposed device is substantially equivalent to the predicate device.