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510(k) SUMMARY

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Device Trade Name

Plasmalink Transfer Pack Container – 2000 mL

Common Name/Usual Name:

Transfer Packs

Classification Name

21 CFR 864.9100 Empty container for the collection and processing of blood and blood components.

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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

81 KSR, Hematology Panel – Empty container for the collection and processing of blood and blood components.

Legally Marketed Devices under which Substantial Equivalence is Being Claimed

Fresenius Kabi is claiming substantial equivalence to the following devices:

- Fenwal Transfer Pack Container – 2000 mL with couplers, which had been on the market prior to May 28, 1976 (preamendment device)
- Fenwal Plasmalink Transfer Pack Container with Luer Adapter and No Outlet Ports (cleared under BK190421)

Device Description

The proposed Plasmalink Transfer Pack Container – 2000 mL (article code 6R2042) is an empty, flexible, single use, non-pyrogenic and sterile fluid path, plastic collection container intended for processing and/or storage of blood and blood components. It consists of a 2000 mL PVC plastic bag having two outlet ports and a bag port that is connected to tubing that has a sampling Y-site, a male luer adapter and luer cap. This code will be generally used for the collection and storage of plasma prior to fractionation.

Statement of Intended Use/Indications for Use

The Plasmalink Transfer Pack Container – 2000 mL is intended for the processing and/or storage of blood and blood components.

Technological Comparison as Compared to the Predicate Devices

The Plasmalink Transfer Pack Container – 2000 mL has the same performance characteristics as the predicate devices, with no change to fundamental scientific technology or principle of operation. Therefore, the technological characteristics of the proposed device and predicate devices are the same.

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Modification to the Existing Device

This application is being submitted for a design change to a pre-amendment device, replacing the connection tubing with one that is already used in a cleared transfer pack. There are no other changes.

Performance Data

The performance of the proposed device was verified by the same methods used in previously cleared submissions and passed the acceptance criteria.

Conclusion

The intended use, fundamental scientific technology, safety and effectiveness of the proposed device remains unchanged from the predicate devices. The verification activities performed in support of the change described in this application provide evidence that the proposed device is substantially equivalent to the predicate devices.