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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: July 13, 2018

I. Submitter

Fresenius Kabi
3 Corporate Drive
Lake Zurich, IL 60047

Contact Person:
Nelson Torres
Sr. Specialist, Regulatory Affairs
Phone: 847-550-0136
Fax: 847-550-2690
Email: nelson.torres@fresenius-kabi.com

II. Device

Trade Name:	DXT
Common or Usual Name:	Separator, Automated, Blood Cell, Diagnostic
Product Code:	81 GKT - Separator, Automated, Apheresis
Classification Regulation:	21 CFR 864.9245
Classification Name:	Automated Blood Cell Separator
Regulation Description:	Automated blood cell separator devices operating by centrifugal or filtration separation principle have been classified by the Center for Biologics Evaluation and Research as Class II devices with Special Controls (Docket 2005N-0017, Final Rule, 30-Nov-07).
Review Panel:	Hematology
Device Class:	Class II
Model Numbers/Article Codes:	X6S9830USB, X6S9830

III. Predicate Device

Trade Name:	DXT
Common or Usual Name:	Separator, Automated, Blood Cell, Diagnostic
510(k) Number:	BK170072
Date Cleared:	September 27, 2017
Product Code:	81 GKT - Separator, Automated, Apheresis
Device Class:	Class II

IV. Device Description

DXT is a software-only system/product that communicates with selected apheresis instruments, as well as external systems and applications (Blood Establishment Computer Systems, Donor Management Systems, Data Management Systems).

Its primary purpose is to send and receive data between connected devices and connected data management systems.

The basic functions of DXT are:

- Receive, store and print apheresis instrument and procedure information from connected apheresis instruments
- Provide procedure information to BECS or other data management systems
- Report status of connected apheresis instruments
- Pre-populate procedure parameters on connected apheresis instruments
- Report operational information based on data received from connected apheresis instruments
- Store apheresis instrument and procedure data that could be used for reporting
- Synchronize time and date between connected instruments
- Ability to manually enter lab data like donor pre-count, donor blood type, actual platelet yield, actual number of platelet products, and donor post-platelet count by the operator to determine collection efficiency

V. Indications for Use

DXT is intended to be used in blood establishments to facilitate networked communication between DXT compatible Fresenius Kabi apheresis devices and BECS or other Data Management Systems. The system can be used for electronic record documentation and remote procedure setup to pre-populate procedure parameters on the appropriate instrument. The information available in the system or provided to BECS or other data management systems can be used for medical decision making such as donor deferral/eligibility decisions. DXT can be deployed with apheresis instruments only as stand-alone or as a middleware application to communicate with an existing external system, e.g., BECS and/or data management systems and an apheresis device.

VI. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of DXT remain the same as previously cleared DXT device. The only difference between the current version of DXT as compared to the previous version is the connectivity with additional apheresis devices, made possible through updates in the system architecture.

Both devices are Microsoft Windows based applications which utilize a web-browser for the User Interface. They both utilize the same common network technologies and both databases were designed using Microsoft SQL Server. Both devices can be deployed with apheresis instruments only as a stand-alone or middleware application to facilitate communication between apheresis devices and existing external systems.

VII. Performance Data

Software verification, System verification, and System validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

VIII. Conclusions

Verification and Validation testing was performed. This testing demonstrates that DXT is safe and effective with respect to its intended use and technological characteristics.