



August 13, 2018

Fresenius Kabi AG  
Attention: Mr. Nelson Torres  
Three Corporate Drive  
Lake Zurich, IL 60047

Re: BK180230

Trade/Device Name: DXT Data Management System, Software Version 3.1  
Regulation Number: 21 CFR 864.9245  
Regulation Name: Automated blood cell separator  
Regulatory Class: Class II  
Product Code: GKT  
Dated: July 13, 2018  
Received: July 16, 2018

Dear Mr. Torres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD  
Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research

Enclosure

**Indications for Use**

510(k) Number: BK180230

Device Name: DXT Data Management System, Software Version 3.1

**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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use  
(21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CBER, Office of Blood Research and Review**

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**Division Sign-Off, Office of Blood Research and Review**