July 9, 2024

Carter BloodCare
Attention: Shankar Goudar
2205 Highway 121 South
Bedford, TX 76021

Re: BK241069

Trade/Device Name:	Blood Bank Information Management System (BBIMS) v3.01
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	April 11, 2024
Received:	April 17, 2024

Dear Shankar Goudar:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.**

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure: Indications for Use

Indications for Use

510(k) Number: BK241069

Device Name: Blood Bank Information Management System (BBIMS) v3.01

Indications for Use: Blood Bank Information Management System (BBIMS) v3.01 is a Blood Establishment Computer Software that is intended for use by trained healthcare professionals for the following blood manufacturing activities:

- Provides a donor-administered or staff entered health history questionnaire
- Transfers donor responses collected from the progressive web application to the system's network
- Provides a staff entered physical assessment
- Provides eligibility information regarding the suitability of a donor making a donation
- Defers donors when they are prohibited from making a donation
- Transfers donor information to Vista® Information System for donation optimization and receives procedure data information from Vista (when using certain automated blood collection systems)
- Provides for maintenance and auditing of donor, donation and unit information
- Provides for generation of donor notification letters
- Provides for defining component preparation, modification and maintenance information
- Provides for defining pooled products (e.g., platelets, cryoprecipitate) into single components
- Transfers test orders and receives test results for all units processed, either through manual entry and/or donor sample testing software systems interfaces
- Provides for labeling components based on Codabar and ISBT standards using HemaTrax® Unity Print Server to print 2x2, 4x2 and 4x4 labels
- Provides for storing patient information during the manual crossmatch/consultation process
- Provides for ordering products and storing information on inventories, orders, shipments, returns and imports

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 (OBRR)

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Division Sign-Off, Office of Blood Research and Review