November 1, 2018

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

Re:	BK180246
Device Name:	Blood Bank Information System (BBIMS) version 2.06.00
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	II
Product Code:	MMH
Dated:	October 26, 2018
Received:	October 26, 2018

Dear Mr. 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. 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 more information.

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) 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

Indications for Use

510(k) Number: BK180246

Device Name: Blood Bank Information System (BBIMS) version 2.06.00

Indications for Use:

Blood Bank Information Management System (BBIMS) v2.06.00 is a Blood Establishment Computer System that is intended for use by trained healthcare professionals for the following blood manufacturing activities:

- Self-administered health history questionnaire to determine donor eligibility using web technology and mobile operating system technology
- Staff entered physical to determine donor eligibility
- Provide information data regarding the suitability of a donor making a donation
- Defer donors when they are prohibited from making a donation
- Store patient information during the manual crossmatch / consultation process
- Store and review test results for all units processed at a blood center, either through manual entry and/or instrument interfaces
- Label components based on Codabar and ISBT standards
- Ability to pool products (i.e., platelets, cryoprecipitate) into single components
- Interfaces with LifeTrak and Vista

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 Device Evaluation (ODE)

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Division Sign-Off, Office of Blood Research and Review