# 510(k) SUMMARY (BK241069)

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**Contact Details:**
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**Device Name:**
Trade Name: Blood Bank Information Management System (BBIMS) v3.01
Classification Name: Blood Establishment Computer Software and Accessories
Device Class: Class II
Product Code: MMH
Panel: Hematology
Regulation Number**:** 21 CFR § 864.9165

**Legally Marketed Predicate Device:**
Predicate #: BK180246
Predicate Trade Name: Blood Bank Information Management System (BBIMS) v2.06.00
Product Code: MMH

**Device Description Summary:**
BBIMS v3.0,1 with its QuickScreen component, is a full-service Blood Bank Information Management System that includes the following features:

- Collection Services
- Donor Relations
- Donation/Unit Entry & Maintenance
- Component Preparation & Maintenance
- Test Results Processing
- Component Labeling
- Reference Laboratory Services
- Product Orders, Shipping, & Inventory
- General Utilities
- Record Auditing Information
- System Administration

**Intended Use/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

**Indications for Use Comparison:**
BBIMS v3.01 and the predicate (BK180246) are Blood Establishment Computer Software intended for use by trained blood bank staff with a self-administered questionnaire intended to be used by donors. BBIMS v3.01 has the same indications of use with the exception that interfaces with LifeTrak will no longer be supported. LifeTrak is a third-party system and does not contribute to the BBIMS design, functions, or operations.

**Technological Comparison:**
BBIMS v3.01 has the same technological characteristics in regard to design, function, and application as the corresponding parts of the referenced predicated device. Testing for BBIMS v3.01 verified the system is safe and effective and performs as well or better than the predicate device when utilized within its intended use.

**Non-Clinical and/or Clinical Test Summary & Conclusions:**
Verification and validation testing was performed at the unit, integration, and functional/system levels including verification testing of program packages and risk control measures. Test case matrices were developed using established procedures for software development.
Carter BloodCare ensures that all safety critical items have been thoroughly tested and can demonstrate that all methods of control for intended use and general implementation hazards have been tested.