

Blood Bank Control System, Version 5.0

VII. 510(k) Summary

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Device:
Proprietary Name: Blood Bank Control System, V5.0 (BBCS)
Common Name: Blood Establishment Computer Software
Classification: not classified, product code 81MMH

Predicates: Blood Bank Control System, V4.1/4.2/4.3 (BK960044)
Donor-ID 2.5 (BK030049)

Device Description:

BBCS V5.0 is a comprehensive blood bank software device that aids in the management of donor and transfusion services.

Intended Use:

BBCS V5.0 is intended to address all phases of donor and transfusion services. The software is designed to assist personnel in recruitment, blood collection services, inventory control, donor testing, shipping/receiving, transfusion services, reference laboratory, and quality assurance, and provides management controls and information services modules for configuration assistance.

Technological Characteristics:

BBCS V5.0 is technologically similar to the predicate device BK960044 in hardware, software, and peripheral usage.

Safety and Effectiveness Data:

BBCS V5.0 has been developed using a defined development process encompassing all phases from design initiation through beta testing, change implementation, and product release.

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Internal (alpha) validation includes system engineer tests, black box and scenario protocol testing, and System Level Testing. Each module in the device is tested under these conditions (black box only applies for modules with screens and/or reports), and any subsequent changes to the modules are assessed for necessary regression testing. The results of the alpha validation demonstrate that BBCS V5.0 meets the requirements for the intended use.

User (beta) validation was conducted at five user facilities, with each critical module specifically evaluated by at least one facility. The results of the beta testing demonstrated that BBCS V5.0 functioned as expected and met the required specifications.

Conclusions:

The conclusions drawn from the alpha and beta validation demonstrate that BBCS V5.0 meets its specifications and functions as expected within its intended use.