VII. 510(k) Summary

Submitter:　　　　　　Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502

Contact:　　　　　　Kathleen Crowder
Director of Quality Assurance and Regulatory Affairs
Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
(253) 333-0046
(253) 333-8247 fax

Device:
Proprietary Name:　BBCS Lab Interface Application V5.0L (BBCS Lab)
Common Name:　　Blood Establishment Computer Software
Classification:　　　not classified, product code 81MMH

Predicate:　　　　　Blood Bank Control System, V4.1/4.2/4.3 (BK960044)

Device Description:
BBCS Lab Interface Application V5.0L is an adjunct device to BBCS V5.0, aiding in the transfer of test results into the Blood Bank Control System.

Intended Use:
BBCS Lab Interface Application V5.0L is intended to assist Laboratory Personnel in the transfer of test results from the lab equipment or data files to the Blood Bank Control System.

Technological Characteristics:
BBCS Lab Interface Application V5.0L is technologically similar to the predicate device in hardware, software, and peripheral usage, with the primary technological difference being the programming language: the PC software for the predicate device was programmed in the C++ language, whereas the device under submission is programmed in the Java language.

Safety and Effectiveness Data:
BBCS Lab Interface Application V5.0L has been developed using a defined development process encompassing all phases from design initiation through beta testing, change implementation, and product release.

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 Lab Interface Application V5.0L meets the requirements for the intended use.

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

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