
Section 5: 510(k) Summary

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

Contact: Jordan Ford
Director of Quality
Blood Bank Computer Systems, Inc.
1002 15th St. SW, Suite 120
Auburn, WA 98001-6502
(253) 333-0046

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Device:
Proprietary Name: ABO Express, Version 2.0.0
Common Name: Blood Establishment Computer Software
Classification: not classified, product code 81MMH

Predicate: Blood Bank Control System, V5.0 (BK040056)
ABO QuickPass, Version 1.0.0 (BK140130)

Device Description:
ABO Express is a software application manufactured by Blood Bank Computer Systems, Inc. (BBCS) that is a comprehensive software device that aids in the management of donor and transfusion services.

Intended Use:
ABO Express is intended to address all phases of donor and transfusion services. The software is designed to assist personnel in collection services, component laboratory, testing, shipping/receiving, transfusion services and reference laboratory.

Technological Characteristics:
ABO Express is technologically similar to the predicate device BK040056 in hardware, software, and peripheral usage, with the primary technological difference being ABO Express can now be accessed through a web portal.

ABO Express is technologically similar to the predicate device BK140130 in that both are accessed through a web portal.

Safety and Effectiveness Data:
ABO Express has been developed using a defined development process

encompassing all phases from design initiation through beta testing, change implementation, and product release.

Alpha validation was comprised of system level testing, integration testing, and unit testing. Each module in the device is tested under these conditions, and any subsequent changes to the modules are assessed for necessary regression testing. The results of alpha validation demonstrate that ABO Express meets the requirements of the intended use.

Beta validation was conducted at two user facilities, using System Level Tests provided by BBCS, but modified by the client for their specific needs. The results of beta testing demonstrated that ABO Express functioned as expected and met the required specifications.

Conclusions:

The conclusions drawn from alpha and beta validation demonstrate that ABO Express meets its specifications and functions as expected within its intended use.