



510(k) Summary

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MANUFACTURER SUBMITTING 510(k) NOTIFICATION

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DEVICE NAME

Proprietary Name: Quality Donor System™ Release 2.1
Common Name: QDS R2.1
Classification Name: Software, blood bank, stand alone products. The product code is 81MMH

PREDICATE DEVICE

Quality Donor System 2004 Release 2.0, 510(k) number BK040062

DEVICE DESCRIPTION

The Quality Donor System™ (QDS) incorporates donor self-administered health history questionnaires that blood center staff review, correct and annotate as necessary. The interview can be administered at the blood collection site or remotely over the Internet. QDS uses Audio-Visual Touch-screen Computer Administered Self Interview technology (AVT-CASI) to allow an untrained donor to respond to health history questions using multimedia prompting and touch-screen responses. The system identifies aberrant donor responses and requires staff to review and comment on such responses. Complete review with documentation as well as complete and consistent answers are required before a donor history card (DHC) can be printed. The DHC remains as the physical control document.

The QDS system is intended to operate on a Wide Area Network (WAN). The entire system is web-based, so that the underlying network protocol is TCP/IP. Individual connections in the network can be hardwired, wireless, leased circuits or over the Internet. In the latter case, connections should use virtual private networking (VPN) to maintain security and data privacy. Some mobile collection sites may not have persistent or permanent connectivity. Such centers will require a small application/database/web server (remote server) to manage

all local clients. The system will synchronize the databases in the main server periodically (e.g., daily) when the remote server is able to connect with the WAN.

INTENDED USE

The Quality Donor System is a comprehensive donor health qualification computer system intended to assist in the blood donor qualification process. QDS is a self-administered donor health history questionnaire that blood center staff reviews, corrects and assists with as necessary. A QDS interview can be administered at the collection site or remotely over the Internet. The system also collects vital signs information and signatures of donors and staff.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE

Technology Characteristic	Quality Donor System™ Release 2.1	Predicate Device
Server platform	Microsoft Windows XP, Windows Server 2003	Microsoft Windows XP, Windows 2000 Server or Windows Server 2003
Client platform	Microsoft Windows XP, Windows Vista	Microsoft Windows XP
Client terminal	Touch-screen tablets	Touch-screen tablets
Peripherals	Bar-code reader, signature pads	Bar-code reader
	Windows compatible printer	Windows compatible printer
Database	SQL Server 2005 Express	Jet database engine (part of Microsoft Windows) (Same as Microsoft Access)
Networking	Standard computer networks; Internet using Secure Socket Layer (SSL)	Standard computer networks

Discussion: The technological characteristics of Quality Donor System Release 2.1 are either identical or similar to those of the predicate device, and do not raise new types of safety or effectiveness questions. The comparison above of the two devices demonstrates equivalence.

SAFETY AND EFFECTIVENESS DATA

The Quality Donor System Release 2.1 was developed using established procedures for software development that include design reviews and software testing. Developers perform both unit tests and system tests on their code. Completed systems are tested and validated internally by non-development staff using formal test procedures and defined scenarios and scripts.

Non-clinical System Testing:

The system was tested with a complete battery of validation and verification tests, the results of which are contained in Section 16.8 (Tab 22) of the 510(k) application. No critical failures were detected.

Clinical System Testing (Beta testing):

The purpose of the beta test is to perform user validation and verification testing of Quality Donor System Release 2.1 in a user environment prior to the final release of the software.

The beta tests were conducted by Mississippi Valley Regional Blood Center to identify any errors, inconsistencies or deviations in the system prior to final release. No critical failures were detected during beta testing. Beta test records are contained in Section 16.9 (Tab 23) of the 510(k) application.

In addition to the formal beta test of the current release of QDS, earlier versions of the system have performed impeccably in the field for over five years in five blood centers and processing well in excess of 1,000,000 donor interviews.

CONCLUSION

Based on a comparison of the Quality Donor System Release 2.1 and the predicate device, QDS is substantially equivalent to the predicate. Based on the outcome of non-clinical tests and of clinical (beta) testing, the system has met the expectations of high product quality and is fit for its intended use.