510(k) Summary

PREPARED June 30, 2004, Revised December 8, 2004

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DEVICE NAME
Proprietary Name: Quality Donor System™ 2004 Release 2.0
Common Name: Blood donor self-interviewing computer software
Classification Name: The product code is 81MMH

PREDICATE DEVICE
Donor-ID version 2.5, 510(k) Number: BK030049

DEVICE DESCRIPTION
The Quality Donor System™ 2004 (QDS) is a computerized system that administers health history questionnaires to potential blood donors and requires trained staff to review and correct them where necessary, resulting in a printed donor history card (DHC). 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 responses and requires staff review and comment of such responses. Complete review as well as complete answers are required before a donor history card (DHC) can be printed. The DHC remains as the physical control document.

QDS runs on standard computer networks with Microsoft-based servers and touch-screen devices as clients. It can also run in standalone mode on a self-contained touch-screen tablet computer. By extensive checking for completeness and consistency of responses as well as monitoring adherence to typical standard operating procedures, QDS helps eliminate significant errors and omissions in the process of pre-donation donor qualification.

INTENDED USE
The Quality Donor System™ 2004 (QDS) is a computer system that improves the consistency of the blood donor qualification process and reduces or eliminates errors and omissions in that

process. QDS incorporates donor self-administered health history questionnaires that blood center staff review, correct and annotate as necessary. The result is a printed donor history card (DHC) and a complete machine readable data file capable of exporting data to other computer systems. 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. Staff use keyboards as well as touch screens. The system identifies aberrant donor responses and requires staff to review and comment on such responses. Complete review 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 purpose of the system is to improve consistency of the blood donor qualification process and reduce or eliminate human errors and omissions, including but not limited to completeness, data transposition, key entry, literacy and communication errors.

Indications for use are the need to reduce or eliminate errors and omissions in the blood donor qualification process.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE

Both QDS and the predicate system operate using Microsoft Windows running on Intel Pentium computers. While QDS uses Windows XP, Windows 2000 Server or Windows Server 2003 and Donor-ID uses Windows 2000 Terminal Server, which is part of Windows 2000, the system characteristics are substantially equivalent. Both systems use touch-screen computer tablets for donor data entry and both systems print donor history cards to Windows-supported printers. Both systems operate over standard computer networks.

SAFETY AND EFFECTIVENESS DATA

The Quality Donor System 2004 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 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 XII 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 QDS 2004 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 XII 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 three years in four blood centers and processing well in excess of 100,000 donor interviews.

CONCLUSION

Based on a comparison of the Quality Donor System 2004 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.