Fifth Dimension
Information Systems
A HAEMONETICS® Company

510(k) Summary

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Manufacturer Submitting 510(k) Notification
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Device Name
Proprietary Name: eQue
Common Name: Donor self administered interview and assessment computer software
Classification Name: Unclassified, Product Code MMH

Predicate Device
Quality Donor System 2004 2.0, 510(k) Number: BK040062, cleared on October 18, 2004.

Device Description
eQue is a computerized system that allows potential donors to complete a self-administered interview through an audio/visual touch-screen kiosk. It is intended to enable the electronic collection of interview data. Trained staff members review the completed interview and any aberrant responses, and record their assessment as to whether the donor can continue.

The system improves the record keeping operations of the center by electronically recording interview and staff assessment results. This information is then available for printing, online review, and for download by external computer systems.

eQue runs on standard computer networks with Microsoft based servers and standard Microsoft computers, laptops, or tablets as clients.

Intended Use
The intended use of eQue is as a computer program that:
- Improves the consistency of the donor qualification process
- Reduces errors and omissions in the process
- Provides a donor self administered questionnaire with optional audio and visual display that an untrained donor can answer

- Allows staff members to complete a questionnaire on behalf of the donor
- Allows staff members to review and correct questionnaires, and record their assessment of donor suitability
- Flags aberrant responses that need to be reviewed and acknowledged by the staff member
- Generates reports for printing or electronic storage
- Generates machine-readable data files that can be exported to other computer systems.

Indications for Use

E-Interview is indicated for the electronic capture and storage of the donor qualification process, thereby reducing errors and omissions.

Comparison of Technological Characteristics to Predicate Device

eQue and the predicate system are both computer programs that run on standard PC hardware connected via standard computer networks. Compatible operating systems are described below:

	Windows 2000	Windows XP	Windows 2003
Predicate	Yes	Yes	Yes
eQue	Yes	Yes	No

Both systems support touch screens for data entry, and both can print reports to Windows supported printers. In addition, the eQue system supports biometric donor identification using a fingerprint scanner.

Non-Clinical Testing

The eQue system was verified through Unit, Secondary, Integration, Stress, Security and Interface testing.

Beta Testing was performed in a plasma collection center, a blood collection center, and a mobile blood collection site. This testing validated the software against the existing legacy system for donor qualification. No critical failures were detected during beta testing.

Conclusions

Based on the comparison of the eQue system and the predicate device, eQue is substantially equivalent to the predicate. The results of testing demonstrate that the device is safe and effective for its intended use.