510(k) Summary

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Date prepared: May 17, 2007
Trade name: ElDorado Donor Doc
Common name: Donor health qualification software
Classification name: Software, blood bank, stand alone products
Substantial equivalence claimed to: E-Interview (eQue) 1.0.0 (BK050060), IDM PRELUDE (BK050014)

Device Description

ElDorado Donor Doc is an interactive computer software application that automates donor screening and pre-donation data collection. ElDorado Donor Doc supports the administration of medical history questionnaires and the collection and assessment of physical exam results. Questionnaires can be administered by trained staff or directly to potential donors. ElDorado Donor Doc provides data quality assurance by automatically identifying missing information that is required for assessment and required supplemental information. The software helps identify and record unsuitable donor medical conditions.

ElDorado Donor Doc supports multi-lingual text display and audio options for questionnaires. Donors' digital signatures and pictures may be stored electronically to enable a paperless process, although records and reports may also be printed. ElDorado Donor Doc may be deployed on a standard PC and tablet PC with touch screen. ElDorado Donor Doc interfaces with donor systems to help eliminate data entry from paper.

Intended Use

ElDorado Donor Doc is a comprehensive donor health qualification computer system that is intended to meet the needs of a blood collection facility. ElDorado Donor Doc provides for the following:

- Electronic collection of donor health information.
- Self-administered questionnaire with optional audio and multi-lingual capabilities.
- Questionnaire that is administered by staff to a donor.
- Identification of and staff assessment of unsuitable donor medical history conditions.
- Required staff review of donor responses and physical exam data.
- Customization and maintenance of questionnaires.
- Printing of records and reports.

- Exchange of donor information with a blood center's software system.
- An optional paperless donor qualification process.
- Comprehensive auditing and security features.
- Identification of potentially aberrant responses.

Technological Comparison

The ElDorado Donor Doc technological characteristics are equivalent to the technologic characteristics of IDM PRELUDE and E-Interview (eQue). ElDorado Donor Doc is technologically similar to the predicate devices in operating system, hardware, and database. The primary technological difference is the programming language.

Safety and Effectiveness Data

ElDorado Donor Doc was developed using an established procedure for software development. The system was verified and validated. Validation test results are available in a supplement to this submission.

Bench (Beta) testing was performed to validate ElDorado Donor Doc. The results of this testing demonstrated that ElDorado Donor Doc met the specified requirements and functioned as expected (see Section 10).

Conclusions

Based on the comparison of ElDorado Donor Doc to predicate devices, ElDorado Donor Doc is substantially equivalent to the predicates. The results of testing demonstrate that the device is safe and effective for its intended use.