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510(K) SUMMARY Revised 11/16/2012

OWNERS PARTICULARS:

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DEVICE NAME:

Trade Name Picture-ID version 2.0
Common Name Picture-ID, eDHQ, MyDHQ and Donation Ticket.
Classification Name Software, blood bank, stand alone products

PREDICATE DEVICE:

Picture-ID version 1.0 BK 090054

DEVICE DESCRIPTION:

Picture-ID is a modular, standalone, computer assisted, online donor identification, self-assisted interview, staff interview, phlebotomy and review application with online workflow-based donor management system that incorporates optional biometric identity verification at any point in the system. There are three main modules in Picture-ID – eDHQ Module, Donor Module and Staff Module. Each module is user configurable and can be independently deployed depending on the requirements of the blood bank. The system allows returning blood donors as well as first time donors who never donated at that blood center. Picture-ID supports multi-lingual text and voice.

eDHQ Module:

The eDHQ Module allows donors to securely complete the DHQ over the internet. Questions are presented in a fillable form (eDHQ) or question by question mode with a Yes, No, Skip responses. Internet transmissions are secured and encrypted over SSL (secured socket

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layer). Completed DHQs are stored on local blood bank database servers, as well as in encrypted barcode, allowing donors to pre-complete DHQs remotely on day of donation, come to the blood or mobile center to donate. The barcode can be printed by the donor or carried digitally in a handheld device, unencrypted and DHQ re-created at site as needed. Forms filled over the internet can only be signed at site.

Donor Module:

The Donor Module is used at the blood center or at mobiles. It can positively verify donor identity using fingerprint, date of birth and gender and then match the identified donor to their picture on file. Options to use State ID or Donor ID is included. Donors can edit their demographic data and be presented with an FDA recognized, AABB Uniform electronic Donor History Questionnaire (DHQ) or similar forms for completion online. Questions are presented in a fillable form (eDHQ) or question by question with a Yes, No, Skip responses. Donors who filled the dhq over the internet are required to positively identify themselves at sites and mobiles, electronically review their answers submitted over the internet and electronically sign the dhq. Electronic signatures enable a paperless workflow process.

Staff Module:

The staff module has several sub-modules. Qualified and trained blood bank staff, interviews the donor in a secured, confidential area. They review the whole dhq and the answers submitted according to their SOPs, write necessary comments and decide to move the donor to the next phase of the process or defer the donor. Picture-ID does not make this decision.

Picture-ID is configurable to reach out to third party 510(k) approved donor management applications via ODBC and SQL query to check if positively identified donors have been deferred in that donor management system.

Electromagnetic Compatibility (EMC) and Internet Transmissions:

The entire system is web services based and incorporates RF wireless technology. Tests for Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) were conducted, and no risk to safety, security and data integrity were identified. Details of tests conducted and their results are separately addressed in Section 17. Donor access to the application can be over LAN (local Area Network), Wan (Wide Area Network) or through the Internet. Internet transmissions are secured and encrypted over SSL (secured socket layer). This allows safe and secured completion of the eDHQ remotely. Completed eDHQs are stored on local database servers allowing donors to pre-complete DHQs remotely on day of donation, come to the blood or mobile center, identify and verify themselves by our three factor authentication, review their eDHQ, sign and submit. This must be done on the day of donation or the donor will have to complete a new DHQ. The reviewed and donor-signed eDHQ is used by qualified and trained blood bank staff, according to their SOPs, to interview the donor in a secured confidential area.



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INTENDED USE:

Picture-ID is a modular, standalone, computer assisted, online donor interview and online workflow-based donor management system that incorporates positive identification with optional biometric identity verification at any stage in the process. It can positively verify donor identity using fingerprint, date of birth and gender and then match the identified donor to their picture on file. Options to use State ID or Donor ID is included. Positively identified donors may be checked for visit eligibility. Donors can enter or edit their demographic data and be presented with an FDA recognized, AABB Uniform electronic Donor History Questionnaire (eDHQ) or similar form, approved by the blood center for completion online. The system provides online form filling and generates an encrypted barcode at the end when the forms are completed over the internet. The barcode is unencrypted and eDHQ re-created at site if required. Completed forms can also be stored in the blood center's database servers.

Qualified and trained blood bank staff can review the DHQ, interview the donor, write comments on any questions, take vitals or mini physicals, approve or defer donors based on their SOPs and perform full phlebotomy and final reviews - all online. This is a paperless process. Extensive field and data validations are performed to ensure data quality. Any blood center-required reading materials can be auto-displayed. Links to Blood center created donor help features, SOPs and other materials are provided when needed. The DHQ can be electronically signed or printed and signed as dictated by blood center policies.

Outputs are provided from the system in files and reports. Output files can be formatted to the requirement of third party blood establishment software and approved databases for upload to their system. Third party applications can apply their checks, balances and controls before importing them to their applications.



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TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE:

Predicate Device

Picture-ID Version 1.0, 510(k) number BK 090054:

Characteristic	Picture-ID Version 2.0 BK 120035	Predicate Device Picture-ID Version 1.0, 510(k) number BK 090054
Biometrics	Three factor authentication. Uses fingerprint identification with donor picture verification	Three factor authentication. Uses fingerprint identification with donor picture verification
Server Platform	Microsoft Windows XP, Server 2003, Server 2008	Microsoft Windows XP, Server 2003, Server 2008
Client Platform	Microsoft Windows XP, Windows 7, Windows 8, Mac.	Microsoft Windows XP
Client Terminal	PCs, Thin Clients, Virtual Desktops, Tablets, iPads, iPhones, Droids, other handheld devices.	Touch-screen PC, or Tablets
Peripherals	Bar-code scanners and readers, Fingerprint scanners, Web-cams, Magnetic Strip Card Readers.	Bar-code readers, Fingerprint scanners, Web-cams, Magnetic Strip Card Readers.
Database	Microsoft SQL Server 2005, 2008	Microsoft SQL Server 2005
Networking	Standard computer networks using TCP/IP. Web Services using Secured Socket Layer (SSL).	Standard computer networks using TCP/IP. Web Services using Secured Socket Layer (SSL).

Discussion:

Technologically the Picture-ID version 2.0 is similar to the predicate device, and does not raise new types of safety or effectiveness questions. The comparison of the above devices in the above tables demonstrates equivalence.



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SAFETY AND EFFECTIVENESS DATA:

Picture-ID incorporates RF wireless technology. Tests of its wireless devices for Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) were conducted by a world-class product compliance and regulatory laboratory certified by American Association for Laboratory Accreditation compliant to ISO/IEC 17025:2005. Their detailed tests and results are attached to Section 17 of this Submission.

Picture-ID was developed using established procedure for software development. Unit tests and systems tests were done by our software team. Completed systems are tested and validated using test scripts for defined scenarios and included in appropriate sections.

Non Clinical System Testing:

The system was tested for validation and verification of functions and the results are contained in Section 16.9.2 of this 510(k) Notification. No critical failures were detected.

Clinical System Testing:

The system was tested in a blood bank user environment and the results are contained in Section 20 of this 510(k) Notification. No critical failures were detected.

Beta Testing and Performance Testing:

Beta Testing was done at the Blood Centers of the Pacific in San Francisco. The results are attached to Section 18 of this 510(k) Notification. No critical failures were detected.

CONCLUSION:

Based on the above comparison of the Picture-ID version 2 to the predicate device, Picture-ID version 2 is substantially equivalent to the predicate. Tests for Electromagnetic Compatibility (EMC) and Electromagnetic Interference (EMI) were conducted, and no risk to safety, security and data integrity were identified. The results of testing demonstrate that the system has met the expectation of high product quality and is safe and effective for its intended use.