10415 Morado Circle
Building III, Suite 300
Austin, TX 78759

510(K) Summary

(in accordance with 21 CFR 807.92)

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Submitter:

Headspring Healthcare
10415 Morado Cir Bldg 3 #300, Morado Cir
Austin, TX 78759

Contact:

Dustin Wells
CEO & President
Phone:(512) 459-2260
Email: Dustin.Wells@headspring.com

Proposed Device Information:

Trade Name	NDDR and CDCS
Common Name	NDDR and CDCS
Product Code	MMH
Classification Regulation	864.9165

Classification Name	Blood Establishment Computer Software and Accessories
Regulation Description	Blood Establishment Computer Software and Accessories

Predicate Device Information:

Trade Name	Cross Donation Check System (CDCS)
Common Name	Cross Donation Check System
510(k) Number	BK140166
Product Code	MMH
Classification Regulation	864.9165
Classification Name	Blood Establishment Computer Software and Accessories
Regulation Description	Blood Establishment Computer Software and Accessories
Review Panel	Hematology
Device Class	Class II

Trade Name	National Donor Deferral Registry (NDDR) (American Blood Resources Association, now Haemonetics Software Solutions)

Common Name	N/A
510(k) Number	BK010012
Product Code	MMH
Classification Regulation	864.9165
Classification Name	Blood Establishment Computer Software and Accessories
Regulation Description	Blood Establishment Computer Software and Accessories
Review Panel	Hematology
Device Class	Class II

Device Description

The proposed NDDR and CDCS is a web-based application that is intended to meet the needs of participating donation centers to check for the presence of recent blood or blood components (including plasma) donations at other donation centers by a prospective donor, as well as check if prospective donors have been deferred by participating donation centers.

The proposed NDDR and CDCS device provides the following features and capabilities:

- Perform donor checks either from a Blood Establishment Computer System (BECS) via a real-time interface to the or manually via web-based screens.
- Provide methods to load basic donation data, including donor identifying information and donation dates from participating centers into the system for their display. Donor information and donation dates can be loaded into the application manually using web-based screens, via periodic data batch uploads, or directly from a BECS using a real- time interface.
- Provide methods to load donor deferral data, including donor identifying information, into the system for display. Deferral information can be loaded into the application manually using web-based screens.
- Allow donor information and donation dates to be updated and deleted, but only by users with the appropriate permission.
- Allow donor deferral information to be added, updated and terminated by users with appropriate permissions.
- Alert a donor check inquirer if a local center hasn't recently uploaded their donor donation dates into the .

- Alert the PPTA staff of a possible situation where a center has sent an unusually large number of donor inquiries.
- Maintain audit history for all donor check inquiries and responses.
- Maintain audit history of stored donor information and donation dates.
- Maintain audit history of deferral check inquiries and responses.
- Maintain audit history of stored deferral information.
- Donation data in the application will be kept for a configurable number of days, after which time the data will be purged from the system. The default is 7 days.
- Deferral data in the application will be kept indefinitely, though individual deferrals may be terminated. Donation inquiry data will be kept for a configurable number of days, after which time the data will be purged from the system. The default is 45 days.
- Username/password security shall be implemented to prevent unauthorized access to data or servers.
- User roles and privileges will be used to limit each user's access to screens and functions.
- A number of pre-defined reports will be provided with the application.

Indications for Use

NDDR and CDCS is a responsive web based software application that is intended to:

- Allow dates of an individual's recent donations to be entered into the system via a web page or submitted to the system via an electronic interface.
- Temporarily store dates of an individual's recent blood or blood component (including Source Plasma) donations at blood or plasma collection facilities.
- Allow blood and plasma collection facilities to retrieve recent dates of a donor's donations of blood or blood components (including Source Plasma) via the web, or through an electronic interface, for the purpose of determining if the frequency of an individual's donations is in compliance with Plasma Protein Therapeutics Association's (PPTA's) standards and applicable regulatory requirements.
- Allow blood and plasma collection facilities to retrieve basic underlying information about a donor to aid and assist in the determination of a donor's eligibility to donate blood or plasma.
- Allow donor deferral information to be added, updated and deleted via a web page.
- Allow blood and plasma facilities to query deferral records stored in the system via the web, or through an electronic interface, to determine if a given donor has been previously deferred, in compliance with Plasma Protein Therapeutics Association's (PPTA's) standards.

Substantial Equivalence

Functionality/Performance

The proposed software device, the NDDR and CDCS, is substantially equivalent to the primary predicate, Predicate 1, Cross Donation Check System (CDCS), where both software devices are web-based computer software programs that are intended to aid and assist blood or plasma donation centers staff in the determination of a donor's eligibility to donate blood or plasma. Both software products use basic identifying information about a donor to provide blood or plasma donation centers staff with historical donation information about the donor for review.

Both the proposed and Predicate 1, Cross Donation Check System (CDCS) software device were subject to the same design controls and use a relational database management system to store all of the application information to help prevent loss or corruption of data. The verification, validation and risk analysis demonstrates that the proposed software device will be as safe and effective as Predicate 1, Cross Donation Check System (CDCS).

The proposed and Predicate 1, Cross Donation Check System (CDCS) are equivalent as follows:

- They are designed to allow the customers to set up the software to meet their own business operations and practices, thus, many of the systems' features are configurable.
- They are installed at a computer data center facility separated from the blood or plasma donation centers and used by the blood or plasma donation centers through the internet.
- They use a relational database management system to store all of the application data to help prevent loss of data or corruption of data.
- The proposed is substantially equivalent to Predicate 1, Cross Donation Check System (CDCS), for use in donation centers to enter and inquire information about donors via the web or through an electronic interface.

The proposed is substantially equivalent to Predicate 2, National Donor Deferral Registry (NDDR) 1.0, for similar functional characteristics.

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- They are installed at a computer data center facility separated from the blood or plasma donation centers and used by the blood or plasma donation centers through the internet.
- They use a relational database management system to store all of the application data to help prevent loss of data or corruption of data.
- The proposed is substantially equivalent to Predicate 2, National Donor Deferral Registry (NDDR) 1.0, for use in donation centers to enter and inquire information about donors via the web or through an electronic interface.

The proposed NDDR and CDCS software device, as well as the indicated predicate devices, is equivalent to or the same with respect to intended use, functionality, performance, technological characteristics as well as safety and effectiveness.

Technological Characteristics

The proposed NDDR and CDCS software device uses similar technology as its predicate devices as summarized below:

- The C# application programming language used by NDDR and CDCS is a modern object-oriented programming language similar to the Java language used by Predicate 1, Cross Donation Check System (CDCS) and Predicate 2, National Donor Deferral Registry (NDDR) 1.0.
- The database used by the proposed NDDR and CDCS is a relational database similar to that used by Predicate 1, Cross Donation Check System (CDCS) and Predicate 2, National Donor Deferral Registry (NDDR) 1.0
- The application server operating system used by NDDR and CDCS is Microsoft Windows, which is a modern operating system similar to that used by Predicate 1, Cross Donation Check System (CDCS) and Predicate 2, National Donor Deferral Registry (NDDR) 1.0

- The application is accessed by web browsers similar to that used by Predicate 1, Cross Donation Check System (CDCS) and Predicate 2, National Donor Deferral Registry (NDDR) 1.0.

The safety aspects of the proposed NDDR and CDCS device have been thoroughly tested in accordance with validation practices as outlined in 820.30 Design Controls. All testing passed. The differences in technology do not pose additional risks as the entire software device application underwent verification, validation and user acceptance testing to ensure safe and effective design. The proposed NDDR and CDCS software device, as well as the indicated predicate devices, is equivalent to or the same with respect to intended use, functionality, performance, technological characteristics as well as safety and effectiveness.

Clinical Trials

Clinical performance testing is not applicable for NDDR and CDCS as it is a software only product.

Performance Bench Testing was performed. See Section 018, Performance Testing - Bench.

Conclusion

The proposed NDDR and CDCS software device was developed in accordance with 820.30 Design Controls as well as the “FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).” The software was thoroughly tested, including verification, validation, and user acceptance (Beta) testing for safety to ensure it will be as safe, as effective, and performed as well as each predicate device’s substantially mapped functionality, when utilized within its intended use and in accordance with labeling, as demonstrated by the testing performed.

Based on the functionality and performance comparison, technological characteristic comparison and the intended use, the proposed software device performs as intended in all aspects of the predicate devices’ mapped functionality characteristics. The safety aspects of the proposed software device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. Therefore, the proposed device is substantially equivalent to the predicate devices in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.