November 18, 2020

Headspring Healthcare, Inc.
Attention: Mr. Dustin Wells
10415 Morado Circle, Suite 300
Austin, TX 78759

Re: BK200526

Trade/Device Name:	National Donor Deferral Registry (NDDR) and Cross Donation Check System (CDCS)
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood establishment computer software and accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	September 25, 2020
Received:	September 28, 2020

Dear Mr. Wells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the **Federal Register**.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Enclosure: Indications for Use

Indications for Use

510(k) Number: BK200526

Device Name: National Donor Deferral Registry (NDDR) and Cross Donation Check System (CDCS)

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.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review (OBRR)

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Division Sign-Off, Office of Blood Research and Review