DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Healthcare-ID, Inc.
Attention: Mr. Steven Sadorf
Vice President of Quality, Human Resource and Finance
1635 Barclay Blvd
Buffalo Grove, IL 60089

Re: BK160039
Trade/Device Name: Donor-ID™ 3.2 (integrated with iCASI App Android)
Regulation Name: Blood Establishment Computer Software
Regulatory Class: Unclassified
Product Code: MMH
Dated: June 1, 2016
Received: June 06, 2016

Dear Mr. Sadorf:

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 (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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, ″Misbranding by reference to premarket notification″ (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Orieji Illoh, MD
Acting 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: BK160039

Device Name: Donor-ID™ 3.2 (integrated with iCASI App Android)

Indications for Use:

Donor-ID™ is a computer system to be used by trained blood center staff to manage donors throughout the blood donation process and to collect and record data. Through the use of computers communicating in real time to the system as it runs on a server, the data obtained for input include: donor demographic data; responses to health history questions (direct oral questioning with optional CASI) and follow up documentation; physical exam results; the phlebotomy data; and donor signature. Optional Computer Assisted Self Interview (CASI) provides the donor with the opportunity to respond to the health history questions 1) at the collection site; or 2) from an external computer accessing the blood center's controlled and secure intranet resulting in a printed document with bar codes that is used upon presentation by the specific donor at the collection site to input the data provided by the donor and to confirm the date. All donor responses through CASI are reviewed by a blood center employee.

Donor-ID™ 3.2 is also integrated with iCASI App iOS/Android technology for use with the donor questionnaire. This is an optional feature.

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 THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review

Division Sign-Off
Office of Blood Research and Review