DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 25, 2016

Sunquest Information Systems, Inc.
Attention: Ms. Amy Beyer
250 S. Williams Boulevard
Tucson, AZ 85711

Re: BK160005
Trade/Device Name: Sunquest Blood Bank and Blood Donor, version 8.0
Regulation Name: Software, Blood Bank, Stand Alone Products
Regulatory Class: Unclassified
Product Code: MMH
Dated: March 23, 2016
Received: March 23, 2016

Dear Ms. Beyer:

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. 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); 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 C. 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: BK160005

Device Name: Sunquest Blood Bank and Blood Donor, v. 8.0

Indications For Use:

Blood Bank

Blood Bank is intended for use by trained health care professionals responsible for transfusion services. It is intended for use to:

- Store records of manufactured and blood product component preparation.
- Print ISBT 128 blood product labels for finished and further processed blood products and products intended for transfer.
- Record the release of manufactured and blood products for infusion.
- Maintain manufactured and blood product inventory for lookback.
- Maintain a historical record of the patient's blood bank and transfusion related data.
- Record testing results of patient specimens and blood products either manually or through instrument interfaces.
- Display data required to assist health care professionals when qualifying patients for electronic crossmatch.

Blood Donor

Blood Donor is intended for use by trained health care professionals responsible for donor services. It is intended for use to:

- Display data that assists health care professionals in making decisions regarding the suitability of donors.
- Generate deferrals to the donor record and maintain donor records.
- Maintain phlebotomy records.

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