DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

LifeSouth Community Blood Centers, Inc.
Attention: Ms. Robin Morris
4039 Newberry Road
Gainesville, FL 32607

Re:	BK160004
Device Name:	Integrated Blood Bank Information System (IBBIS), Version 4.0
Regulation Name:	Stand Alone Blood Bank Software
Regulatory Class:	Unclassified
Product Code:	MMH
Dated:	March 24, 2016
Received:	March 24, 2016

Dear Ms. Morris:

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. Please note: CBER does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 Small Manufacturers, International and Consumer Assistance 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: BK160004

Device Name: Integrated Blood Bank Information System (IBBIS) Version 4.0

Indications for Use:

IBBIS Version 4.0 is a computerized system of programs to aid in the entry, tracking, and lookback of information related to blood donor registration, donor eligibility determination (including a computer-assisted self interview (CASI), technician review of donor responses, capture of donor physical results, automatic deferral creation), blood donation collection, blood product processing, labeling, and manipulation (e.g., fractionating, splitting, freezing, irradiating), product quarantine and release, product distribution (shipping and receiving), and donor testing, including the ability to electronically transfer testing results from an outside testing facility. While the majority of the programs within IBBIS v4.0 are intended to be used by trained blood bank personnel, the CASI functionality included in IBBIS v4.0 is intended to be used by donors at the collection site to respond to the health history questionnaire with or without assistance from blood bank personnel.

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 Device Evaluation (ODE)

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Division Sign-Off, Office of Blood Research and Review