



August 14, 2018

Mediware Information Systems, Inc.
Attention: Mr. Jon Moeckel
11711 West 79th Street
Lenexa, KS 66214

Re: BK180200

Trade/Device Name: LifeTrak® 2018
Regulation Number: 21 CFR 864.9165
Regulation Name: Blood Establishment Computer Software and Accessories
Regulatory Class: Class II
Product Code: MMH
Dated: July 9, 2018
Received: July 9, 2018

Dear Mr. Moeckel:

This letter corrects our substantially equivalent letter of July 3, 2018.

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.

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for more information.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/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: BK180200

Device Name: LifeTrak® 2018
Software, Blood Bank, Stand Alone

Indications for Use:

LifeTrak® is a comprehensive, modular, computerized system intended to be used by trained personnel as a tool in the management of data processes performed by staff at blood centers and high-volume testing services. User access to individual modules is controlled through defined access levels. Individual staff may be actively engaged in functions that encompass the following:

- Dynamic donor eligibility status
- Register, track, and audit donations and deferrals
- On-line health history, physical findings, and collection process
- Inter-active donor questionnaire (staff and/or donor/remote donor)
- HLA/RBC search and match
- Donor schedules
- Component production and modification
- Testing
- Labeling
- Imported Blood Processing
- Inventory Management
- Distribution
- Material Check-In
- Offline Data Entry (Re-entry if downtime)
- LifeTrak® is usable with wired/wireless networks supporting TCP/IP protocols

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Division Sign-Off, Office of Blood Research and Review