October 18, 2018

MAK-SYSTEM SA International Group
Attention: Mr. Simon Kiskovski
10 Avenue de la Grande-Armée
Paris, France 75017

Re: BK180232

Trade/Device Name:	Patient Health Software (P.H.S) Version 2.0
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	October 16, 2018
Received:	October 16, 2018

Dear Mr. Kiskovski:

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: BK180232

Device Name: Patient Health Software (P.H.S) Version 2.0

Indications for Use:

The Patient Health Software (PHS) application is a modular, stand-alone blood transfusion, testing laboratory software dedicated to: blood centers or community blood banks with transfusion services centers, hospitals transfusion services, reference labs, testing laboratories. PHS is designed to aid and assist qualified and trained personnel to support the operations within their facilities. PHS software supports single, centralized multi-sites and multi-organizations to be used centrally or in stand-alone.

PHS undertakes process controls for testing laboratory and transfusion service operations on testing on patients, manages, tracks and determines the suitability of the blood components and blood derivatives to reduce human error and contribute to patient safety.

PHS is intended to address all phases of laboratory activities and/or transfusion services operations at laboratory department, transfusion service departments, hospital wards and patient bed side. Functionality is provided for:

- Patient identification at bed side and patient record management;
- Supporting Patient immunohematology, virology, histocompatibility laboratory testing used for suitability and including reagent quality control;
- Supporting human leukocyte antigen (HLA) laboratory testing for suitability;
- Blood components preparation, release and labeling (ISBT 128);
- Blood components selection, testing and issue of blood components under normal and emergency conditions, including serological crossmatch, electronic crossmatch and remote crossmatch of blood components;
- Tracking of blood components disposition, record transfusion details and related outcome and record keeping of patient transfusion history for lookback.

PHS interfaces with Health Information Systems, laboratory testing instruments, BECS, Laboratory Information Systems (LIS) and blood storage devices.

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

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Division Sign-Off, Office of Blood Research and Review