



June 11, 2025

MAK-SYSTEM Group Ltd.
Attention: Stéphane Sajot
1 Bartholomew Lane
EC2N 2AX London United Kingdom

Re: BK251188
Trade/Device Name: Patient Health Software (P.H.S) v11.0.0.0
Regulation Number: 21 CFR 864.9165
Regulation Name: Blood establishment computer software and accessories
Regulatory Class: Class II
Product Code: MMH
Dated: March 28, 2025
Received: March 28, 2025

Dear Stéphane Sajot:

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. 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 available 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**.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809 ; medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Wendy Paul, 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: BK251188

Device Name: Patient Health Software (P.H.S) v11.0.0.0

Indications for Use:

The eTraceLine / Patient Health Software (P.H.S) 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. eTraceLine/P.H.S is designed to aid and assist qualified and trained personnel to support the operations within their facilities. eTraceLine/P.H.S software supports single, centralized multi-sites and multi-organizations to be used centrally or in standalone.

eTraceLine/P.H.S undertakes process controls for laboratory testing and transfusion service operations, manages, tracks and determines the suitability of the blood components and blood derivatives to reduce human error and contribute to patient safety.

eTraceLine/P.H.S intended to address all phases of laboratory activities and/or transfusion services operations at the laboratory department, transfusion service departments, hospital wards, and patient bedside. Functionality is provided for:

- Patient identification at bedside and patient record management;
- Supporting Patient immunohematology, virology, histocompatibility laboratory testing used for suitability and including reagent quality control;
- Supporting HLA, HNA, and HPA laboratory testing;
- Blood components preparation, release, and labelling (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 inventory, transformation, disposition, record transfusion details and related outcomes, and record-keeping of patient transfusion history for lookback;
- Supporting therapeutic bleed orders.

eTraceLine/P.H.S interfaces with Hospital Information Systems (HIS), laboratory testing instruments, BECS, Laboratory Information Systems (LIS), and blood storage devices.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

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 Blood Research and Review (OBRR)

Division Sign-Off, Office of Blood Research and Review