November 3, 2023

MAK-SYSTEM Group Ltd.
Attention: Stephane Sajot
1 Bartholomew Lane
London
United Kingdom

Re: BK230986/0

Trade/Device Name:	ePROGESA v5.0.3
Regulation Number:	21 CFR 864.9165
Regulation Name:	Blood establishment computer software and accessories
Regulatory Class:	Class II
Product Code:	MMH
Dated:	August 11, 2023
Received:	August 14, 2023

Dear Stephane 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**.

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 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.

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,

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: BK230986/0

Device Name: ePROGESA v5.0.3

Indications for Use:

ePROGESA is a modular, stand-alone blood bank, plasma centers, and blood transfusion service software application that is specially designed to meet the needs of organizations collecting blood, plasma, platelets, cord blood, and/or transfusion services organizations to aid/assist qualified and trained personnel to support the major operations within their facilities.

ePROGESA is designed to undertake typical blood bank operations on fixed and mobile sites including but not limited to session planning and recruitment of donors; donor eligibility status including deferrals management, interactive donor health questionnaire (Computer Assisted Self Interviews (CASI)), also called SAHH feature, completed by staff or donors or remote donors and reviewed by a blood center-trained staff; immunization traceability for plasma donors; donation collection; component preparation and transformation; donor and donation laboratory testing; blood unit stage release; blood inventory, and distribution of blood products and manufactured products, product quality control including bacterial screening; blood products lookback and donor surveillance; HLA/RBC searching and matching.

ePROGESA is also intended to support typical blood transfusion operations of order management, patient management, inventory selection, testing, further manufacturing, release, and distribution of blood products and manufactured products, track product disposition and keep transfusion history. Orders and reporting of patient results can be managed by interface with the Hospital Information System.

ePROGESA also includes interfaces for the National Deferred Donor Register (NDDR), collection and manufacturing devices, LIMS, quality control and Laboratory Instruments which assist trained personnel in the transfer and integration of data to the ePROGESA software.

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 (OBRR)

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Division Sign-Off, Office of Blood Research and Review