MAK-SYSTEM

enabling individuals to save lives

Volume 005

510(k) Summary

ePROGESA v5.0.3

Traditional 510(k) Summary

ePROGESA v5.0.3

In accordance with 21 C.F.R. 807.87(h), a 510(k) Summary is included that meets the conditions as outlined for a 510(k) summary in 21 C.F.R. 807.92.

Date of Summary	11th August, 2023

SUBMITTER INFORMATION

510(k) Owner/Submitter	MAK-SYSTEM Group Ltd. 1 Bartholomew Lane EC2N 2AX London, UK Email: regulatory@mak-system-net
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DEVICE INFORMATION

Trade Name	ePROGESA
Common Name	Software for Blood Banks, Plasma Centers and Blood Transfusion Centers
Device Classification Regulation	21 C.F.R. 864.9165
Device Classification Name	Blood Establishment Computer Software and Accessories
ProductCode	MMH
Device Class	II

PREDICATE DEVICE INFORMATION

Predicate Device	ePROGESA v5.0.1 (BK080002)
Prior Related Submissions	No prior submission for this device

No reference devices were used in this submission.

DEVICE DESCRIPTION

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. ePROGESA is intended to aid/assist qualified and trained personnel to support the major operations within their facilities.

ePROGESA is built using JAVA technology and n-tier web architecture which enables the system to be used by a variety of organizations, made available in a client's dedicated environment.

ePROGESA is intended to be interfaced with 3rd party systems through standard network connections. ePROGESA supports centralized multi-sites organization structure.

The main modules available in ePROGESA include:

- Session Planning and Recruitment
- Donation Collection Management
- Donor Management
- Donor, Donation and Blood Component Laboratory Testing
- Blood Component Preparation
- Product Inventory Management
- Quality Control Management
- Distribution Management
- Traceability and Haemovigilance Management
- Consumable Management
- Patient Management
- Patient Transfusion Service Management
- Lookback and Surveillance Management
- Interfaces
- Utilities
- Report Management
- Security
- System Configuration

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The intended use of ePROGESA v5.0.3 is substantially equivalent to the predicate devices as both software devices are intended to aid/assist qualified and trained personnel to support the major operations, including but not limited to, donor registration, donor collection management, product suitability, and inventory and distribution.

The difference in the technological characteristics between the predicate and subject devices are substantially equivalent as the fundamental scientific technology and intended use is unchanged.

The proposed ePROGESA v5.0.3 is substantially equivalent to the legally marketed device ePROGESA v5.0.1 in intended use, features and technological characteristics.

NON-CLINICAL PERFORMANCE

Extensive software verification and validation testing were conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices*. The software is considered a major Level of Concern as it qualifies as the Blood Establishment Computer Software.

The verification testing was performed at MAK-SYSTEM by conducting predefined verification scripts that contain scenarios created to comprehensively test the device.

Validation testing was conducted in order to ensure that ePROGESA software application meets its intended use, including critical safety requirements. The process was performed based on the scripts prepared and traced to the functional requirements and to the risk analysis. Validation activities consists of Alpha, Platform and Beta (user site) testing.

Alpha and Platform testing took place at MAK-SYSTEM and Beta testing was performed prior final software release in a user environment.

CLINICAL PERFORMANCE

No clinical testing was performed in support of this premarket notification.

CONCLUSION

ePROGESA v5.0.3 is as safe and as effective as the predicate device. The ePROGESA v5.0.3 has substantially the same same intended use and similar indications, as well as technological characteristics and principle of operations as its predicate device.

The technological differences do not raise any questions of safety and effectiveness as the performance data demonstrates that ePROGESA v5.0.3 performs as intended in the specified use conditions.

Based on the testing results, MAK-SYSTEM concludes that ePROGESA v5.0.3 meets the expectations, fits its intended use and is substantially equivalent to its predicate device.