# Section 5

## 510(k) Summary

Patient Health Software (P.H.S) v11.0.0.0

# Traditional 510(k) Summary

# P.H.S v11.0.0.0

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.

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| **Date of Summary** | Mar. 28, 2025 |

## SUBMITTER INFORMATION

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| **510(k) Owner/Submitter** | MAK-SYSTEM Group Ltd. |
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## DEVICE INFORMATION

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| **Trade Name** | Patient Health Software (P.H.S) |
| **Common Name** | Transfusion Safety and Blood Traceability Software for Health Care Organizations |
| **Device Classification Regulation** | 21 C.F.R. 864.9165 |
| **Device Classification Name** | Blood Establishment Computer Software and Accessories |
| **Product Code** | MMH |
| **Device Class** | II |

## PREDICATE DEVICE INFORMATION

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| **Predicate Device** | Patient Health Software (P.H.S) Version 2.0 (BK180232) |
| **Prior Related Submissions** | No prior submission for this device |

No reference devices were used in this submission.

## DEVICE DESCRIPTION

The 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, and Histocompatibility and Immunogenetics (H&I) laboratories. P.H.S is designed to aid and assist qualified and trained personnel to support the operations within their facilities. P.H.S software supports single, centralized multi-sites and multi-organizations to be used centrally or in standalone.

P.H.S is built using JAVA technology and 3-tier web architecture, which enables the system to be used by a variety of organizations, made available in a client's dedicated environment. .

P.H.S is intended to be interfaced with 3rd party systems through standard network connections. P.H.S supports centralized multi-site and multiorganization structures, including both on-premise and on-cloud deployment.

The main modules available in P.H.S include:
- Patient Management
- Patient and Blood Component Laboratory Testing
- Patient Transfusion Management
- Blood Components and Derivatives Inventory Management
- Distribution Management
- Haemovigilance Management
- Transformation and Pooling Management
- Consumables Management
- Blood Tracking System (BTS)
- Positive Patient Identification (PPID)
- Security
- Utilities

P.H.S can also be configured in LIS mode. When configured in LIS mode, the P.H.S functionalities are limited to the test orders and results created for patient's and blood donations.


## 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 is 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.

## COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The intended use of P.H.S v11.0.0.0 is substantially equivalent to the predicate device as both software devices are intended to aid/assist qualified and trained personnel to support the operations within their facilities, including but not limited to, patient management, patient transfusion management, transformation and pooling management, patient and blood components laboratory testing, hemovigilance, distribution management, and others.

The proposed software device, P.H.S v11.0.0.0, uses similar technology to its predicate device. Technological upgrades, including addressing obsolescence and enabling cloud deployment, enhance the subject device, and none of these pose device safety or effectiveness concerns.

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

These differences are assessed through risk analysis and tested to ensure that they do not pose any risk to the substantial equivalence between the predicate and the subject device.

The proposed Patient Health Software (P.H.S) v11.0.0.0 is substantially equivalent to the legally marketed device Patient Health Software (P.H.S) Version 2.0 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, *Content of Premarket Submission for Device Software Functions.* The Documentation Level of P.H.S is Enhanced Documentation as it qualifies as the

Blood Establishment Computer Software.

No security-related hazards persist at an unacceptable risk level, as substantiated by justifications, and ongoing risk management protocols ensure perpetual oversight and enhancement during both production and post-production stages.

The non-clinical testing, conducted to support this submission, consisted of verification and validation testing activities. The validation includes Alpha and Beta (user site) testing events. Both Alpha and Beta testing data support the safety and effectiveness of the subject device and demonstrate that P.H.S v11.0.0.0 performs as intended in the specified use conditions.

## CLINICAL PERFORMANCE

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

## CONCLUSION

The modified Patient Health Software (P.H.S) v11.0.0.0 is as safe and as effective as the predicate device. This Traditional 510(k) is submitted to modify legally a marketed, predicate device.

The P.H.S v11.0.0.0 has substantially the same intended use and similar indications. The technological differences do not raise any questions of safety and effectiveness as these differences are assessed through risk analysis and tested to ensure that they do not pose any risk to the substantial equivalence between the predicate and the subject device.

MAK-SYSTEM concludes that Patient Health Software (P.H.S) v11.0.0.0 meets the expectations, fits its intended use, and is substantially equivalent to its predicate device.