MAK-SYSTEM
INTERNATIONAL GROUP

Volume 5

510(k) Summary

P.H.S v2.0

510(k) Summary

5.1 Submitter

Company Name	MAK-SYSTEM SA International Group
Company Address	10 Avenue de la Grande-Armée 75017 Paris France
Contact person	Simon Kiskovski - CEO Email: simon.kiskovski@mak-system.net Phone: +33 1 44 09 04 04
Date prepared	July 17, 2018

5.2 Device

Trade Name	Patient Health Software (P.H.S) v2.0
Common Name	Blood Establishment Computer Software and Accessories
Classification Name	Blood Establishment Computer Software and Accessories
Product Code	MMH
Classification Regulation	21 CFR 864.9165
Device Class	Class II

5.3 Predicate devices

	Manufacturer	Product	510(k) number
Predicate device 1	MAK-SYSTEM	Patient Health Software (P.H.S) 1.0	BK060035
Predicate device 2	Mediware Information Systems, Inc.	HCLL™ Transfusion 2015 R2	BK160066

5.4 Device description

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 provides following features:

- Patient administration including electronic data capture of demographic data,
- Mother/Baby Link,
- Inventory Management for blood components, derivatives and consumables, including Multiple-site Inventory,
- Blood components storage management including electronic data capture with blood storage equipment,
- Quarantine components and derivatives,
- Transformation and pooling,
- Reception of blood components and derivatives from other organizations including electronic data capture of blood components,
- Blood components and derivatives Delivery/Shipping,
- Patient Sample Management,
- Patient identification at bed side,
- Laboratory Management for Patients including test result electronic data capture,
- Laboratory testing of blood components and derivatives,
- Component Laboratory Testing, including release testing such as bacterial screening of platelets,
- Pre and post testing laboratory,
- Serological (incl. remote) and Electronic Cross-Match,
- Histocompatibility and Immunogenetics,
- Blood components and derivatives Distribution and Returns,
- Transfusion Documentation and history,
- Hospital Order Management (test, blood components and derivatives, consumables) and electronic data capture of orders,
- Quality Control,
- Blood components labeling ISBT128,
- Haemovigilance,
- Incident / Accident management,
- Invoicing,
- Statistics and reports,
- Auditing.

PHS has been designed to operate in a N-Tier open architecture. PHS can be deployed as Thin or Thick configurations and use of Internet Explorer.

5.5 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.

5.6 Comparison of technological characteristics with the predicate devices

Element of comparison	A Patient Health Software (P.H.S) v2.0	B Patient Health Software (P.H.S) 1.0 (BK060035)	C HCLL™ Transfusion 2015 R2 (BK160066)	Comparison results
Workstation Operating System	• Microsoft Windows 8, 10, IE11	• Microsoft Windows NT • Microsoft Windows 98 • Microsoft Windows 2000 • Microsoft Windows XP	Unknown	A/B: Equivalent
Workstation RAM	8 GB	• 256 Mb • 512 Mb	Unknown	A/B: Equivalent
Workstation Processor	• Intel Core i3 • Intel Core i5	• Intel Pentium III • Intel Pentium IV	Unknown	A/B: Equivalent
Application Server Operating System	• Microsoft Windows 2016 Server • Unix: Linux Red Hat 4 • Unix: Centos 7 • Unix: AIX 7 • Unix: Solaris 10	• Microsoft Windows 2003 • Oracle Solaris 10 • Linux Red Hat 4	Unknown	A/B: Equivalent
Application Server RAM	• 32 Gb • 256 Gb	• 4 Gb • 8 Gb	Unknown	A/B: Equivalent
Application Server Processor	• Intel Core i7 • Intel Xeon • IBM Power 7 • Oracle Sparc	• AMD Opteron • Oracle Sparc • Intel Pentium IV	Unknown	A/B: Equivalent
JAVA Application Server Licence	• Tomcat 7, 8 • Weblogic 11, 12	• RDP • Sun Microsystems SUN ONE • JBOSS	Unknown	A/B: Equivalent
Database Server Operating System	• Microsoft Windows 2016 Server • Unix: Linux Red Hat 4 • Unix: Centos 7 • Unix: AIX 7 • Unix: Solaris 10	• Microsoft Windows 2003 • Oracle Solaris 10 • Linux Red Hat 4 • IBM AIX	• Microsoft Windows 2008 • Microsoft Windows 2003	A/B/C: Equivalent
Database Server RAM	• 32 Gb • 256 Gb	• 4 Gb • 8 Gb	Unknown	A/B: Equivalent
Database Server Processor	• Intel Core i7 • Intel Xeon • IBM Power 7 • Oracle Sparc	• AMD Opteron • Oracle Sparc • IBM Power PC • Intel Pentium IV	Unknown	A/B: Equivalent
Database Server Licence	• Oracle 11g, 12 c	• Oracle Database 10g • InterSystems Caché 5	• Microsoft SQL 2008 • Microsoft SQL 2005 • Microsoft SQL 2000	A/B/C: Equivalent
Application language	Java	• Inprise Delphi • Java	• Visual Basic • C++ Com • .Net • C#	A/B/C: Equivalent

Element of comparison	A Patient Health Software (P.H.S) v2.0	B Patient Health Software (P.H.S) 1.0 (BK060035)	C HCLL™ Transfusion 2015 R2 (BK160066)	Comparison results
Network	Ethernet TCP/IP	Ethernet TCP/IP	Unknown	A/B: Equivalent

The proposed software device, P.H.S v2.0, is substantially equivalent to the software devices B. Patient Health Software (P.H.S) 1.0 (BK060035) and C. HCLL™ Transfusion 2015 R2 (BK160066).

The proposed PHS v2.0 uses similar technology as its predicate devices. While there are minor differences in technological characteristics and principles of operations, none of these differences raise new type of safety and effectiveness questions.

The proposed Patient Health Software (P.H.S) v2.0 is as safe, effective and equivalent to the predicate devices.

5.7 Performance Data

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 Submissions for Software Contained in Medical Devices". The software was considered as a "major" level of concern, since the software qualifies as 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 design requirements as specified in the SDS documents.

Validation testing was conducted in order to ensure that PHS software meet its intended use including critical safety requirements. This process was performed based on the scripts prepared and traced to the functional requirements and to the risk analysis. Validation testing consists of Alpha and Beta (user site) testing.

Alpha testing took place at MAK-SYSTEM following the software installation procedure, installation qualification steps and execution of the scenarios related to the functional requirements.

Beta testing was performed prior final software release in a user environment at the Institute for Transfusion Medicine - ITxM (Pittsburgh, USA).

During verification activities, all failed occurrences were tracked, corrected and retested. There were no failed occurrences during Alpha and Beta testing.

The results of software verification and validation testing are included in volume 16 of our submission.

5.8 Conclusions

Patient Health Software (P.H.S) v2.0 was developed in accordance with Design Controls (21 CFR 820.30) and using established software development procedures.

Risk analysis has been performed and all hazards have been mitigated. Each of the implemented mitigations was verified with acceptable results. Verification and validation testing was conducted to ensure it will be as safe, as effective, and that it will perform as well as each of the predicate devices, within its intended use and in accordance with its labeling.

Beta testing data supports the safety and effectiveness of the device and demonstrates that PHS v2.0 will perform as intended in the specified use conditions.

Based on the test results, MAK-SYSTEM concludes that Patient Health Software (P.H.S) v2.0 met the expectations, fit its intended use and is substantially equivalent to its predicate devices.