MAK-SYSTEM
INTERNATIONAL GROUP

Section 6
510(k) SUMMARY

MAK-SYSTEM
INTERNATIONAL GROUP

Patient Health Software
P.H.S Version 1.0

510(k) Submission
Dated May 31, 2006

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PREMARKET NOTIFICATION 510(k) SUMMARY

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6.1 – ESTABLISHMENT INFORMATION

A. Premarket Notification submitter:

Company Name: **MAK-SYSTEM SAS International Group**

Company Address: 10 Avenue de la Grande Armée
75017 Paris
France

Owner # : 9025329
Registration # : 9613847

B. Contact person:

Simon Kiskovski - CEO
+ 33.1.44.09.04.04

6.2 – DEVICE INFORMATION

A. Device Name and classification:

Trade Name: Patient Health Software – Version 1.0
Common Name: P.H.S
Classification Name: Software, Transfusion Service, stand alone software

B. – Device product code and class determination

Classification Regulation: **Not classified**
Device Class: **Unclassified**
Product Code: **MMH**

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6.3 – LEGALLY MARKETED PREDICATE DEVICE

The identified legally marketed predicate devices are:
- Cerner's Corp. PathNet Blood Bank Transfusion device BK950053
- Windgates Technologie's SafeTrace Tx BK980023

as described into Section 5.

6.4 – DEVICE DESCRIPTION

The PHS application is modular, stand-alone blood transfusion software, manufactured by MAK-SYSTEM.

PHS is designed to support typical blood transfusion operations and transfusion service activities, including, but not limited to patient testing lab, blood component, derivatives and consumable inventory, testing, further blood transformation and distribution from inventories including electronic cross-match and remote cross-match to appropriate transfusion services.

Specifically:
- Patient administration including electronic data capture of demographic data
- Mother/Baby Link
- Inventory Management for blood products, manufactured products and consumables, including Multiple-site Inventory
- Quarantined Products
- Transformation and pooling
- Receive blood product and manufactured product from other organizations including electronic data capture of blood products
- Delivery/Shipping
- Patient Sample Management
- Laboratory Management for Patients including test result electronic data capture
- Pre and post testing laboratory
- Serological (incl. remote) and Electronic Cross-Match
- Product Distribution and Returns
- Transfusion Documentation and history
- Hospital Order Management (test, blood products and manufactured products, consumables) and electronic data capture of orders
- Haemovigilance

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- 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.

6.5 INTENDED USE

The submitted device, P.H.S is a software application which is intended for use in blood banks or hospitals with transfusion services and laboratories. It is intended for use by qualified and trained personnel to support the major operations within their facilities generally to establish and maintain appropriate data.

P.H.S intends to aim and facilitate the operations by establishing and maintaining data related to patient administration, order management, laboratory testing and result entry, transfusion management, product inventory management, distribution management, manufacturing management, haemovigilance management.

It also assists the trained professionals in making decisions regarding suitability or qualifying patients for electronic crossmatch.

The software functionality of the Patient Health Software (P.H.S.) application is substantially equivalent to the Cerner PathNet application.

6.6 – COMPARISON OF TECHNOLOGICAL CHARACTERISTICS TO PREDICATE DEVICE

The operating system, database and hardware characteristics of the PHS application are different but substantially equivalent to the predicate devices as 6.3 above.

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Patient Health Software (P.H.S) OS/Database/Hardware Environment	Cerner Corp. - PathNet OS/Database/Hardware Environment	Wyndgate Technologies - SafeTrace Tx OS/Database/Hardware Environment
Application Server operates on Microsoft Windows 2003 or on Sun Solaris or Linux Red Hat and SUN One, JBOSS.	Cerner PathNet operates on standard Digital Equipment Corporation (DEC) and IBM Unix Hardware and Operating Systems.	Application Server operates on Microsoft Windows NT Server Version 3.51 or higher.
Database Server operates on Microsoft Windows 2003 or on Sun Solaris or on Linux Red Hat or on AIX. Oracle RDBMS or Caché RDBMS.	Cerner PathNet operates on person-centric relational database.	Database Server operates on Oracle Relational Database Management System version 7.3 or higher and Oracle SQLNET 2 or higher.
Client with Microsoft Windows NT, 2000, XP	Cerner PathNet client side user interface is through Microsoft Windows 95 or Windows NT or terminals.	Client Processing Environment with Microsoft Windows 95 or higher or Windows NT Version 3.51 or higher, and Oracle SQLNET 2 or higher.

Patient Health Software (P.H.S.) Other Technological Characteristics	Cerner Corp. - PathNet Other Technological Characteristics	Wyndgate Technologies - SafteTraceTx Other Technological Characteristics
Application Language- Inprise Delphi, Java	Application Language -COBOL, C, CCL	Application Language- Inprise Delphi
Database - Oracle Relational Database Management System or Caché Intersystems	Database - Person-centric relational database	Database - Oracle Relational Database Management System
User Interface - Windows 98, 2000, XP	User Interface – Windows 95, Windows NT and terminals	User Interface - Windows 95 and Windows NT
Architecture – Highly scaleable, multi-tier client server or Thin Client	Architecture – Highly scaleable, multi-tier client server	Architecture - Highly scaleable, multi-tier client server
Platforms – Open industry standard	Platforms – Open industry standard	Platforms - Open industry standard

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Performance data

6.7 – NON CLINICAL SYSTEM TESTING

System test are performed as part of the verification activities in order to ensure that the PHS software meet it's intended use including critical safety requirements. This process is used based on scripts prepared and traced to the functional requirements and to the hazard analysis.

This activity takes place at MAK-SYSTEM following software installation procedure, installation qualification steps and execution of the test scripts. The test cases encompass the electronic data capture based on data samples that are build in order to meet the corresponding requirements and safety critical requirements.

The summary of the results of these test cases are including in section 15.3.

Prior to the completion of the system testing, all fail occurrences were resolved, corrected and retested. All safety critical issues were corrected and retested.

6.8 – CLINICAL – BETA TESTING

Beta test are performed in a user environment prior final software release. The Florida Blood Service organization located in Tampa was in charge to execute the beta test scripts in order to promote the identifications of errors, inconsistencies and deviations in P.H.S software. As unexpected arose, they were tracked and addressed and corrected by MAK-SYSTEM. All failed occurrences were corrected and retested.

The result of this testing are included in section 15.5.

6.9 – CONCLUSION OF NON-CLINICAL AND CLINICAL TESTING

PHS software was developed using established software development procedures. The non-clinical system testing and the clinical beta testing processed demonstrate that the PHS software meet the requirements for its intended use and its functional requirements.

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As result of the above, MAK-SYSTEM believe that Patient Health Software version 1.0 met the expectations, fit its intended use and is substantially equivalent to its predicate device.