510(K) SUMMARY

In accordance with 21 CFR 807.92, Mediware submits the following 510(k) Summary for HCLL™ Transfusion 2015 R2, blood bank stand-alone software device:

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510(K) SUMMARY

MANUFACTURER SUBMITTING 510(K) NOTIFICATION:

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11711 W. 79th Street.
Lenexa, KS, 66214

CONTACT PERSON:

Jon Moeckel
Regulatory Compliance Specialist
Mediware Information Systems, Inc.
11711 W. 79th Street
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DEVICE NAME:

Proprietary Name: HCLL™ Transfusion 2015 R2
Common Name: Software, Blood Bank, Stand Alone
Classification Name: Unclassified

PREDICATE DEVICE:

HCLL™ Transfusion, 2012

DEVICE DESCRIPTION:

HCLL™ Transfusion 2015 R2 is a standalone blood bank software device that aids in the management of single, multi-site, or centralized transfusion services. HCLL™ Transfusion 2015 R2 provides customized control processes for transfusion management of all procedures and testing on products and patients to reduce human error and enhance the ability to assure patient product safety. Functionality is provided for patient identification and management, specimen tracking, inventory control, tracking product modification, product labeling, testing/test management, issuing of product and data review.

HCLL™ Transfusion 2015 R2 provides an optional web-enabled user interface that is designed to work with Microsoft Internet Explorer to allow access to the existing HCLL™ Transfusion application.

510(K) SUMMARY

INDICATIONS FOR USE:

HCLL™ Transfusion 2015 R2 is intended to address all phases of transfusion services activities, and assists transfusion service personnel:

- Manipulate and label products
- Print ISBT 128 blood labels
- Perform electronic crosshatch
- Issue blood products under normal and emergency conditions
- Receive and test patient and unit specimens
- Interface to blood bank testing instruments (bi-directional)
- Interface to blood storage devices (bi-directional)

COMPARASON OF FUNCTIONAL CHARACTERISTICS TO PREDICATE DEVICE:

The intended use and technological characteristics of HCLL™ Transfusion 2015 R2 are comparable to the predicates. The systems are fully scalable to the enterprise level and the relational database management systems, operating systems and hardware are substantially equivalent.

FUNCTIONAL CHARACTERISTICS:	
HCLL™ Transfusion 2012	**HCLL™ Transfusion 2015 R2**
Provides customized control processes for transfusion management of all procedures and testing on products and patients to reduce human error and enhance the ability to assure Patient and product safety.	Provides customized control processes for transfusion management of all procedures and testing on products and patients to reduce human error and enhance the ability to assure Patient and product safety.
Patient: • Manual or electronic admission, registration, discharge, and/or transfer • Manual or electronic orders • Product issued • Transfusion records • Edit, special instructions, comments, search and inquiry • Record antigens, antibodies not associated to internal testing • Notification of autologous, directed or reserved products • Merge duplicate patient records	Patient: • Manual or electronic admission, registration, discharge, and/or transfer • Manual or electronic orders • Product issued • Transfusion records • Edit, special instructions, comments, search and inquiry • Record antigens, antibodies not associated to internal testing • Notification of autologous, directed or reserved products • Merge duplicate patient records
Specimen:	Specimen:

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• Track patient and/or unit specimens throughout the system including acceptability, age, status, transfer between facilities and discard • Link to one or more armband identifiers to a single patient • Optional reuse of specimen numbers	• Track patient and/or unit specimens throughout the system including acceptability, age, status, transfer between facilities and discard • Link to one or more armband identifiers to a single patient • Optional reuse of specimen numbers
Inventory: • Receive allogeneic, Autologous, directed and reserved products • Receive products into multiple facilities and multiple locations with each; move products between locations • Add, view, or edit product comments • Assign products to a patient • Add or remove special testing • Destruction methods • Product return form issue or to shipper • Storage devices can be governed or exempted from rules regarding time limits out of the blood bank • Transfer products, derivatives, or reagents • Interface to stand-alone blood bank storage devices (bi-directional)	Inventory: • Receive allogeneic, Autologous, directed and reserved products • Receive products into multiple facilities and multiple locations with each; move products between locations • Add, view, or edit product comments • Assign products to a patient • Add or remove special testing • Destruction methods • Product return form issue or to shipper • Storage devices can be governed or exempted from rules regarding time limits out of the blood bank • Transfer products, derivatives, or reagents • Interface to stand-alone blood bank storage devices (bi-directional)
Product Modification: • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division • Divided product modification	Product Modification: • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division • Divided product modification
Labeling: • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division • Divided product modification	Labeling: • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division • Divided product modification
Testing: • Test result entry	Testing: • Test result entry

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• Test result invalidation or cancel • Worksheet specific blood bank procedures • Alerts when patient associated to Autologous, directed or reserved products • Up to six (6) worksheets used simultaneously in a single or batch result entry process • Select to see all blood bank procedures (tests) for a patient • Antibodies, Antigens and Patient Instructions are displayed, Comments displayable • Ability to “Perform Only” or “Perform/Verify test results” • Reagent acceptability, testing usage, and required schedules of quality control • Alert of patient suitability for electronic cross match • Electronic cross match • Interface to blood bank instruments (bi-directional)	• Test result invalidation or cancel • Worksheet specific blood bank procedures • Alerts when patient associated to Autologous, directed or reserved products • Up to six (6) worksheets used simultaneously in a single or batch result entry process • Select to see all blood bank procedures (tests) for a patient • Antibodies, Antigens and Patient Instructions are displayed, Comments displayable • Ability to “Perform Only” or “Perform/Verify test results” • Reagent acceptability, testing usage, and required schedules of quality control • Alert of patient suitability for electronic cross match • Electronic cross match • Interface to blood bank instruments (bi-directional)
Issue: • Routine issue • Emergency Issue, single screen, with specific criteria • Manually, Bar-coded, or by product selection search • Antibodies, Antigens and patient instructions are displayed, comments displayable	Issue: • Routine issue • Emergency Issue, single screen, with specific criteria • Manually, Bar-coded, or by product selection search • Antibodies, Antigens and patient instructions are displayed, comments displayable
Quality: • On-line review, single or batch, of all unsatisfactory or unexpected data and system overrides	Quality: • On-line review, single or batch, or all unsatisfactory or unexpected data and system overrides
Web-enabled: • Optional web-enabled user interface that is designed to work with Microsoft Internet Explorer to allow access to the existing HCLL™ Transfusion application	Web-enabled: • Optional web-enabled user interface that is designed to work with Microsoft Internet Explorer to allow access to the existing HCLL™ Transfusion application

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SAFETY AND EFFECTIVENESS DATA:

HCLL™ Transfusion 2015 R2 was developed using an established design control process for software development. The product was subjected to extensive verification and validation testing including system testing to ensure the product meets its intended use including safety critical requirements. Nonclinical (alpha) testing was performed by Mediware and demonstrates that HCLL™ Transfusion 2015 R2 meets the requirements for intended use.

Clinical/user site (use acceptance) testing was conducted to validate HCLL™ Transfusion 2015 R2. The results of user sites testing demonstrated that HCLL™ Transfusion 2015 R2 meets the required specifications and functioned as expected with no degradation in response times.

CONCLUSIONS:

Mediware Information Systems, Inc. concludes that HCLL™ Transfusion 2015 R2 is substantially equivalent to the predicate devices listed in that it has the same intended use with similar features and capabilities. HCLL™ Transfusion 2015 R2 provides some minor extensions of the functional capability. Testing was conducted as required by Mediware's Design Control Validation and Verification processes to evaluate these changes in functional capabilities of HCLL™ Transfusion 2015 R2. The results of this testing demonstrates that HCLL™ Transfusion 2015 R2 performs as expected and that the minor changes in functional capabilities do not effect safety or effectiveness.

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