



510(K) SUMMARY

In accordance with 21 CFR 807.92, WellSky submits the following 510(k) Summary for WellSky® Transfusion 2022 R3, blood bank stand-alone software device:

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510(K) SUMMARY**MANUFACTURER SUBMITTING 510(K) NOTIFICATION:**

WellSky Corporation
11300 Switzer Rd
Overland Park, KS 66210

CONTACT PERSON:

Jon Moeckel
Sr. Regulatory Compliance Manager
WellSky Corporation
11300 Switzer Rd
Overland Park, KS

DEVICE NAME:

Proprietary Name: WellSky® Transfusion 2022 R3
Common Name: Software, Blood Bank, Stand Alone
Classification Name: Class II

PREDICATE DEVICE:

HCLL™ Transfusion, 2015 R2

DEVICE DESCRIPTION:

WellSky® Transfusion 2022 R3 is a standalone blood bank software device that aids in the management of single, multi-site, or centralized transfusion services. WellSky® Transfusion 2022 R3 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.

WellSky® Transfusion 2022 R3 provides an optional web-enabled user interface that is designed to work with Microsoft Internet Explorer to allow access to the existing WellSky® Transfusion solution.

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INDICATIONS FOR USE:

WellSky® Transfusion 2022 R3 is intended to address all phases of transfusion services activities, and assists transfusion service personnel:

- Maintain a reliable patient database.
- Manually and electronically register, admit, and transfer patients.
- Manually and electronically receive patient orders.
- Manipulate and label products.
- Print ISBT 128 Blood Labels.
- Perform Electronic Crossmatch.
- Issue blood products under normal and emergency conditions.
- Receive inventory.
- Ship specimens, reagents, derivatives, and blood products.
- 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 WellSky® Transfusion 2022 R3 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 2015 R2	WellSky® Transfusion 2022 R3
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: <ul style="list-style-type: none"> • Manual or electronic admission, registration, discharge, and/or transfer 	Patient: <ul style="list-style-type: none"> • Manual or electronic admission, registration, discharge, and/or transfer

<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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
<p>Specimen:</p> <ul style="list-style-type: none"> • 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 	<p>Specimen:</p> <ul style="list-style-type: none"> • 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
<p>Inventory:</p> <ul style="list-style-type: none"> • 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) 	<p>Inventory:</p> <ul style="list-style-type: none"> • 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)
<p>Product Modification:</p> <ul style="list-style-type: none"> • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division 	<p>Product Modification:</p> <ul style="list-style-type: none"> • User-definable product processing (leuko-reduction, irradiation, washing, freezing, etc.) • Pooling and poling modification (add to or remove from pool) • Product division

<ul style="list-style-type: none"> • Divided product modification 	<ul style="list-style-type: none"> • Divided product modification
<p>Labeling:</p> <ul style="list-style-type: none"> • 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 	<p>Labeling:</p> <ul style="list-style-type: none"> • 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
<p>Testing:</p> <ul style="list-style-type: none"> • Test result entry • 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) 	<p>Testing:</p> <ul style="list-style-type: none"> • Test result entry • 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)
<p>Issue:</p> <ul style="list-style-type: none"> • 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 	<p>Issue:</p> <ul style="list-style-type: none"> • 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
<p>Quality:</p>	<p>Quality:</p>

<ul style="list-style-type: none">On-line review, single or batch, of all unsatisfactory or unexpected data and system overrides	<ul style="list-style-type: none">On-line review, single or batch, or all unsatisfactory or unexpected data and system overrides
Web-enabled: <ul style="list-style-type: none">Optional web-enabled user interface that is designed to work with Microsoft Internet Explorer to allow access to the existing HCLL™ Transfusion application	Web <ul style="list-style-type: none">User interface that is designed to work with a web browser to allow access to the existing WellSky® Transfusion application

SAFETY AND EFFECTIVENESS DATA:

WellSky® Transfusion 2022 R3 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 WellSky and demonstrates that WellSky® Transfusion 2022 R3 meets the requirements for intended use.

Clinical/user site (use acceptance) testing was conducted to validate WellSky® Transfusion 2022 R3. The results of user sites testing demonstrated that WellSky® Transfusion 2022 R3 meets the required specifications and functioned as expected with no degradation in response times.

CONCLUSIONS:

WellSky Corporation concludes that WellSky® Transfusion 2022 R3 is substantially equivalent to the predicate devices listed in that it has the same intended use with similar features and capabilities. WellSky® Transfusion 2022 R3 provides some minor extensions of the functional capability. Testing was conducted as required by WellSky's Design Control Validation and Verification processes to evaluate these changes in functional capabilities of WellSky® Transfusion 2022 R3. The result of this testing demonstrates that WellSky® Transfusion 2022 R3 performs as expected and that the minor changes in functional capabilities do not affect safety or effectiveness.