510(K) SUMMARY

In accordance with 21 CFR 807.92, WellSky submits the following 510(k) Summary for WellSky™ Blood – Emergency Issue 2020 R1, medical device accessory:

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MANUFACTURER SUBMITTING 510(K) NOTIFICATION:

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CONTACT PERSON:

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DEVICE NAME:

Proprietary Name: WellSky™ Blood – Emergency Issue 2020 R1
Common Name: Software, Blood Bank
Classification Name: Class II

PARENT DEVICE:

HCLL™ Transfusion, 2015 R2

DEVICE DESCRIPTION:

WellSky™ Blood – Emergency Issue 2020 R1 is a Blood Establishment Computer Software (BECS) Accessory that provides the ability to perform an Emergency Issue. WellSky Blood – Emergency Issue provides customized control processes for Emergency Issue management to reduce human error and enhance the ability to assure patient product safety. Functionality is provided for patient identification, support of emergency patient safety protocols, issue blood products under emergency conditions and confirmation scan of correct transfusion slip on correct unit.

WellSky™ Blood – Emergency Issue 2020 R1 can be used to emergency issue products on a mobile device and desktop workstation.

WellSky™ Blood – Emergency Issue 2020 R1 is not a standalone system. WellSky™ Blood Emergency Issue 2020 depends on HCLL™ Transfusion to obtain patient data, as well as to send unit information, safety data, and regulatory inspection step data back to HCLL™ Transfusion. will communicate bi-directionally through intelligent integration messages to obtain patient information and to update and record the Emergency Issue in HCLL™ Transfusion. HCLL™ Transfusion stores this information in the Transfusion database, exactly now Transfusion processes and stored this data currently. WellSky Blood Emergency Issue does not maintain data.
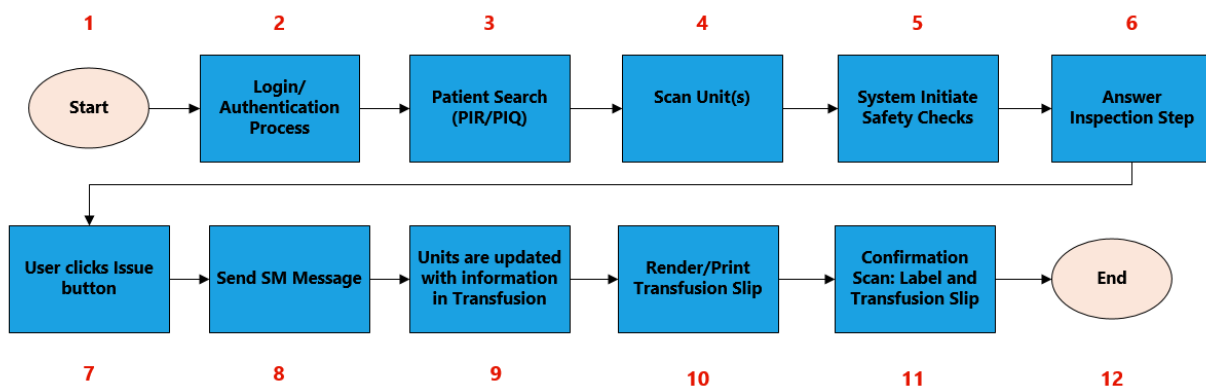
WellSky Blood – Emergency: Patient Search
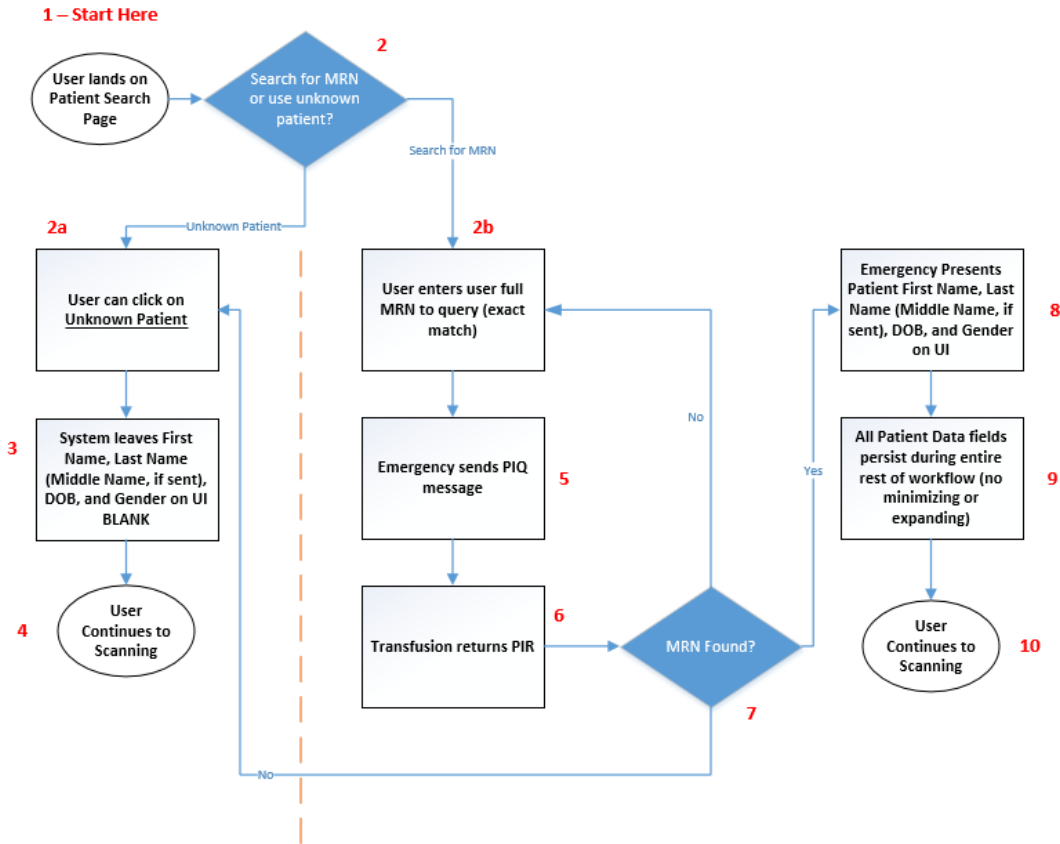
Step	Workflow Step Description
1	User logs into WellSky Blood - Emergency on their browser via mobile device.
2	User authentication process initiates/completes.
3	User can search for a patient via their MRN (primary patient identifier) or follow the workflow for Unknown Patient.
4	WellSky Blood – Emergency Issue will return known MRN (s) and present via UI.
5	User can scan a unit label or multiple unit. This is the label already attached to the unit (and contains Unit ID, Product Code, ABO, Expiration date).
6	WellSky Blood – Emergency Issue shall run a safety check on unit selected against patient. These are safety checks, e.g. gender vs. ABO. Blood Drop shall inform user if

	unit does not meet safety requirements and prevent issue (or as dictated by facility SOPs). Note: Safety checks are based on ABO, gender, childbearing age, and product type, per facility SOPs. WellSky Blood – Emergency Issue recommends a standard based on the following.
7	User shall be prompted (required) to answer if each unit passes inspection or not. If unit does not pass inspection, user shall be prevented from issuing; the "No" answer must be documented.
8	For the safety check, status check, and inspection step (=N), overrides may be allowed in some cases, per facility SOPs. This will depend on safety rules, and configuration set up. Overrides shall need to be documented.
9	Multiple user can choose to work on the same patient (for different units) at the same time (e.g., scan, print, inspection step, confirm, etc.).
10	User can continue to issue products for the same patient (product quantity is not limited).
11	Users can remove units via Emergency, before final issue is complete for that particular patient.
12	User shall complete issue for that patient. Upon issue, WellSky Blood – Emergency Issue shall communicate with Transfusion. In Transfusion, user will see that patient has the associated unit(s), specified as an Emergency Issue status.
13	WellSky Blood – Emergency Issue shall allow printing of the transfusion slip for that particular unit(s) and patient.
14	User will complete confirmation scans: scanning unit label and transfusion slip, to ensure the label and transfusion slip match. This is configurable per facility SOP.
15	Users can initiate a reprint for transfusion slip(s) for the current patient presented (as needed).
16	All workflow steps are subject to Clinical and Hazard Analysis/Risk assessment.
17	All steps include UX (User Experience) design.

18	All information will be processed in Transfusion and stored in Transfusion, in sync with current Transfusion functionality and according to current Transfusion database schema.

510(K) SUMMARY

INDICATIONS FOR USE:

WellSky™ Blood – Emergency Issue 2020 R1 is intended to support the performance of HCLL™ Transfusion by enabling that device to perform according to its intended use by addressing all phases of transfusion services activities, and assist transfusion service personnel they relate to the emergency issue of blood products:

- Allow for emergency patient safety protocols.
- Issue blood products under emergency conditions.
- Confirmation scan of correct transfusion slip on correct unit.
- Use of emergency issue products on a mobile device and desktop workstation.

COMPARASON OF FUNCTIONAL CHARACTERISTICS TO PARENT DEVICE:

WellSky™ Blood – Emergency Issue 2020 R1 is intended to supplement the performance of HCLL™ Transfusion by adding additional functionality and usage to assist transfusion service personnel as they relate to the emergency issue of blood products:

FUNCTIONAL CHARACTERISTICS:	
HCLL™ Transfusion 2015 R2	**WellSky™ Blood – Emergency Issue 2020 R1**
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: • Known patient	Patient: Known Patient Query only
Inventory: • Receive allogeneic, Autologous, directed and reserved products	Inventory: Product Selection
Issue: • Emergency Issue	Issue: Emergency Issue only

Quality:	Quality:
• Review of all system overrides.	Safety Checks overrides as configured
Web-enabled:	Web-enabled:
•	Yes – Only option

SAFETY AND EFFECTIVENESS DATA:

WellSky™ Blood – Emergency Issue 2020 R1 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™ Blood – Emergency Issue 2020 R1 meets the requirements for intended use.

Clinical/user site (use acceptance) testing was conducted to validate WellSky™ Blood – Emergency Issue 2020 R1. The results of user sites testing demonstrated that WellSky™ Blood – Emergency Issue 2020 R1 meets the required specifications and functioned as expected with no degradation in response times.

Product Type: Red Blood Cells (RBCs) + Whole Blood			
WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule (s)**
RBC Rule 1 1. If clinical gender = male; and 2. Product type = Red Cells; and 3. Unit is **O neg**; THEN. 4. DO NOT present as safety check.	**Male**	**No**	**N/A**
RBC Rule 2 1. If clinical gender = male; and 2. Product type = Red Blood Cells; and 3. ABO/Rh is **any other ABO/Rh** besides O neg or O pos, THEN. 4. Apply safety check message as a **HARD STOP**:	**Male**	**No**	**N/A**

Product Type: Red Blood Cells (RBCs) + Whole Blood

WellSky Standard	Gender	Configurable?	Configurable Rule (s)
a) Message: "ABO/Rh is not suitable. Remove unit."			

RBC Rule 3
 	
1. If clinical gender= male, and.
2. Product type = Red Blood Cells, and.
3. ABO/Rh is **O pos**, THEN:
4. Apply a safety check for a **SOFT STOP**.
  a) **Message:** "ABO/Rh requires an override."
  b) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available
	Male	**Yes**
		
		If the Facility chooses another configuration besides RBC Rule 3, they must choose either RBC Rule 10 or RBC Rule 11.
		
		Only one rule can be in place at a given time: RBC Rule 3, 11, OR 12.
		
		The configurable rule is based on no stop, hard, stop, or soft stop, with all other variables besides the above being consistent with RBC Rule 3.
			RBC Rule 11
			
			1. If gender = male; and
			2. Product type = Red Blood Cells; and
			3. Unit ABO/RH is **O Pos**, THEN:
			4. Apply safety check that is a **HARD STOP**.
			  a. **Message:** "ABO/Rh is not suitable. Remove unit."
			
			OR
			
			RBC Rule 12
			
			1. If clinical gender = male; and
			2. Product type = Red Cells; and
			3. Unit is **O pos**; THEN.
			4. DO NOT present as safety check.

RBC Rule 4 1. If clinical gender = female; and	**Female Childbearing = Yes**	**Yes** RBC Rule 4 is configurable for AGE only	Same as RBC Rule 4, calculated for different age

Product Type: Red Blood Cells (RBCs) + Whole Blood

WellSky Standard	Gender	Configurable?	Configurable Rule (s)
2. Product type = Red Blood Cells; and 3. Patient age = 55 'childbearing' or younger at time of PIR/PIQ; and 4. Unit is **O neg**; Then: 5. DO NOT present as safety check.		Childbearing age, once configured, applies to all rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ). All other variables besides age are consistent with RBC Rule 4.	
RBC Rule 5 1. If clinical gender = female; and 2. Product type = Red Blood Cells; and 3. Patient age = 55 'childbearing' or younger at time of PIR/PIQ query; and 4. ABO/Rh is **any other ABO/Rh** besides O neg or O pos, THEN: 5. Apply safety check message as a **HARD STOP**: a) Message: "ABO/Rh is not suitable. Remove unit."	**Female Childbearing = Yes**	**Yes** RBC Rule 5 is configurable for AGE only Childbearing age, once configured, applies to all rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ). All other variables besides age are consistent with RBC Rule 5.	Same as RBC Rule 5, calculated for different age

Product Type: Red Blood Cells (RBCs) + Whole Blood			
WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule (s)**

RBC Rule 6
1. If clinical gender= female, and.
2. Product type = Red Blood Cells; and
3. Patient age = 55 'childbearing' or younger at time of PIR/PIQ query; and
4. ABO/Rh is **O pos**, then:
5. Apply a safety check for a **SOFT STOP**.
  a) **Message:** "ABO/Rh requires override for childbearing age females."
  b) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available
	Female Childbearing = Yes	**Yes**
		
		RBC Rule 6 is configurable for AGE only
		
		Childbearing age, once configured, applies to all rules with childbearing age as part of the rule(s).
		
		Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ).
		
		All other variables besides age are consistent with RBC Rule 6.
			Same as RBC Rule 6, calculated for different age

RBC Rule 7 1. If clinical gender = female; and 2. Product type = Red Cells; and 3. Patient age = 56 '**NOT** childbearing' years or older at time of PIR/PIQ; and 4. Unit is **O neg**, THEN: 5. DO NOT present as safety check.	**Female, Childbearing = No**	**Yes** RBC Rule 7 is configurable for AGE only Childbearing age, once configured, applies to all rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ).	Same as RBC Rule 7, calculated for different age

Product Type: Red Blood Cells (RBCs) + Whole Blood			
WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule (s)**
		All other variables besides age are consistent with RBC Rule 7.	

RBC Rule 8
 	
1. If clinical gender = female; and
2. Product type = Red Blood Cells; and
3. Patient age = 56 '**NOT** childbearing' or older at time of PIR/PIQ query; and
4. ABO/Rh is **O pos**, THEN:
5. Do not present a safety check.
	Female, Childbearing = No	**Yes**
		
		RBC Rule 8 is configurable for AGE
		
		Childbearing age, once configured, applies to <u>all</u> rules with childbearing age as part of the rule(s).
		
		Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ).
		
		Rule 8 is also configurable for a soft stop (rule 13) (if standard no safety check isn't preferred). Only Rule 8 or Rule 13 can be implemented at once.
			RBC Rule 13
			
			1. If clinical gender = female; and
			2. Product type = Red Blood Cells; and
			3. Patient age = 56 '**NOT** childbearing' or older at time of PIR/PIQ query; and
			4. ABO/Rh is **O pos**, THEN:
			5. Apply a safety check for a **SOFT STOP**.
			  b) **Message:** "ABO/Rh requires an override."
			  c) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available

Product Type: Red Blood Cells (RBCs) + Whole Blood			
WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule (s)**
RBC Rule 9 1. If clinical gender = female; and 2. Product type = Red Blood Cells; and 3. Patient age = 56 '**NOT childbearing**' or older at time of PIR/PIQ query; and 4. ABO/Rh is **any other ABO/Rh** besides O neg or O pos, THEN: 5. Apply safety check message as a **HARD STOP**: 6. Message: "ABO/Rh is not suitable. Remove unit."	**Female, Childbearing = No**	**Yes** RBC Rule 9 is configurable for AGE only Childbearing age, once configured, applies to <u>all</u> rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ). All other variables besides age are consistent with RBC Rule 10.	Same as RBC Rule 9 calculated for different age
RBC Rule 10 1. If clinical gender = Unknown. 2. And product type = Red Cells. 3. And patient DOB = unknown; or 4. Known DOB; and 5. Unit ABO/Rh is **O neg OR O pos**; then 6. Follow rules for Female Patient with DOB = Childbearing age.	**Unknown** Whereas Unknown is because user followed Unknown patient workflow, OR gender is returned from Transfusion, but DOB does not include DOB.	**No**	**N/A**

Product Type: Plasma			
WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule(s)**
Plasma Rule 1 1. If clinical gender = Male, Female, or Unknown 2. Product type = Plasma; and 3. Patient DOB = any; and 4. Plasma **Group = A and AB**; then 5. Do not present any safety message.	Male, Female, or Unknown Whereas Unknown is because user followed Unknown patient workflow; or Transfusion returned partial data and did not return gender; or Transfusion returned a value for gender other than male or female.	Yes, if Rule 3 is chosen, then Rule 3 supersedes both Rule 1 and Rule 2	**Plasma Rule 3** 1. If clinical gender = Male, Female, or Unknown 2. Product type = Plasma; and 3. Patient DOB = any; and 4. Plasma **Group = AB** then; 5. Do not present a safety message for Group AB; AND 6. Present hard stop for any other ABO: Message: "ABO/Rh is not suitable. Remove unit."
Plasma Rule 2 1. If clinical gender = Male, Female, or Unknown 2. Product type = Plasma; and 3. Patient DOB = any; and 4. Plasma is NOT **Group = A OR AB**; then 5. Present hard stop: 6. Message: "ABO/Rh is not suitable. Remove unit."	Male, Female, or Unknown Whereas Unknown is because user followed Unknown patient workflow; or Transfusion returned partial data and did not return gender; or Transfusion returned a value for gender other than male or female.		See above

Product Type: Platelets			
Rules for WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule(s)**
Platelet Rule 1 1. If clinical gender = Male 2. And product type = Platelets. 3. And patient DOB = any; and 4. Unit is <u>any ABO</u>; and 5. Is **Rh negative**; then 6. Do not present any safety message.	**Male**	**No**	**N/A**
Platelet Rule 2 1. If clinical gender = Female 2. And product type = Platelets. 3. And patient DOB = any; and 4. Unit is <u>any ABO</u>; and 5. Is **Rh negative**; then 6. Do not present any safety message.	**Female (childbearing = any)**	**No**	**N/A**
Platelet Rule 3 1. If clinical gender = Unknown; and 2. And product type = Platelets. 3. And patient DOB = any; and 4. Unit is <u>any ABO</u>; and 5. Is **Rh negative**; then 6. Do not present any safety message.	**Unknown** Whereas Unknown is because user followed Unknown patient workflow; or Transfusion returned partial data and did not return gender; or Transfusion returned a value for	**No**	**N/A**

Product Type: Platelets

Rules for WellSky Standard	Gender	Configurable?	Configurable Rule(s)
	gender other than male or female.		
Platelet Rule 4 1. If clinical gender = Male; and 2. And product type = Platelets. 3. And patient DOB age =any; and 4. Unit is any ABO; and 5. Unit Rh positive; then 6. Do not present any safety message.	**Males**	**No**	**N/A**

Platelet Rule 5	Female (childbearing age = yes)	Yes	Platelet Rule 6
1. If clinical gender = Female; and 2. And product type = Platelets. 3. And patient DOB = childbearing age (55 or younger at time of PIR/PIQ query); and 4. Unit is <u>any ABO</u>; and 5. Unit **Rh positive**; then 6. Apply a safety check for a **SOFT STOP**. 　d) **Message:** "ABO/Rh requires an override." 　e) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available		Platelet Rule 5 is configurable for Childbearing Age and Safety Check(s). Childbearing age, once configured, applies to <u>all</u> rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ). Facility has a soft stop (standard as per Platelet Rule 5), or Facility can choose to not have a safety check presented at all (Platelet Rule 6). Facility must have either Platelet Rule 5 OR Platelet Rule 6 implemented. Platelet Rule 5 is also referred to as "ignoring the RH for Platelets" – however ignoring RH for Rh Negative is a moot point (any gender), as Rh-Negative Platelets don't ever trigger a safety notification. All other variables besides age and	1. If clinical gender = Female. 2. And product type = Platelets. 3. And patient DOB = [childbearing age] or younger 4. Unit is any ABO; and 5. Unit is RH positive; or 6. Do not present a safety check.

	WellSky™ Blood – Emergency Issue 2020 R1
WellSky logo	**Traditional 510(k): Device Submission**

Section 5	Page | 18

Product Type: Platelets			
Rules for WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule(s)**
		safety checks consistent with Platelet Rule 5.	
Platelet Rule 7 1. If clinical gender = Female; and 2. And product type = Platelets. 3. And patient DOB for females = not childbearing age (56 or over at time of PIR/PIQ query); and 4. Unit is <u>any ABO</u>; and 5. Unit <u>Rh positive</u>; then 6. Do not present any safety message.	**Female (childbearing age = no)**	**Yes** Platelet Rule 7 is configurable for AGE only. Childbearing age, once configured, applies to <u>all</u> rules with childbearing age as part of the rule(s). Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ). All other variables besides age are consistent with Platelet Rule 7.	Same as Platelet Rule 7, calculated for different age

Product Type: Platelets			
Rules for WellSky Standard	**Gender**	**Configurable?**	**Configurable Rule(s)**

Platelet Rule 8
 	
1. If clinical gender = Unknown; and
2. Product type = Platelets; and
3. Patient DOB = unknown; and
4. Unit Rh positive; then
7. Apply a safety check for a **SOFT STOP**.
   f) **Message:** "ABO/Rh requires an override."
   g) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available
	Unknown
	
	Whereas Unknown is because user followed Unknown patient workflow.
		Yes
		
		Facility has soft stop (standard as per Platelet Rule 8), or Facility can choose to have a soft stop (Platelet Rule 9).
		
		Soft stop in this case is also referred to as "ignoring the Rh".
			Platelet Rule 9
			
			1. If clinical gender = Unknown; and
			2. And product type = Platelets.
			3. And patient DOB age = any; and
			4. Unit is any ABO; and
			5. Unit Rh positive; then
			6. Do not present any safety message.

Product Type: Platelets

Rules for WellSky Standard	Gender	Configurable?	Configurable Rule(s)

Platelet Rule 10
 	
1. If clinical gender = Unknown; and
2. The DOB = childbearing age (55 or younger at time of PIR/PIQ query); and
3. Product type = Platelets; and
4. Unit Rh positive; then
5. Apply a safety check for a **SOFT STOP**.
    h) **Message:** "ABO/Rh requires an override."
    i) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available
	Unknown
	
	Whereas Unknown is because we received partial data back from Transfusion and do not know gender but DO know DOB.
		Yes
		
		Platelet Rule 10 is configurable for AGE and safety check/soft stop.
		
		Facility must choose Platelet Rule 10 or Platelet Rule 11.
		
		Childbearing age, once configured, applies to all rules with childbearing age as part of the rule(s).
		
		Childbearing age is calculated based on Facility-defined age (DOB at time of PIR/PIQ).
		
		All other variables besides age and safety check or soft stop, are consistent with Platelet Rule 10.
		
		Soft stop in this case is also referred to as "ignoring the Rh".
			Same as Platelet Rule 10, calculated for different age
			
			And
			
			Platelet Rule 11
			
			1. If clinical gender = Unknown; and
			2. And product type = Platelets.
			3. And DOB = childbearing age (55 or younger at time of PIR/PIQ query); and
			4. Unit is any ABO; and
			5. Unit Rh positive; then
			6. Do not present any safety message.

Product Type: Cryoprecipitate "Cryo"

WellSky Standard	Gender	Configurable?	Configurable Rule(s)
Cryo Rule 1 1. If clinical gender = male, female, or unknown; and 2. Product type = cryoprecipitate; and 3. DOB = any; and	**Male, Female, Unknown**	**No**	**N/A**

4. ABO/Rh = any; then 5. Do not apply as safety check. Any type can be given without concern to ABO/Rh, gender, or DOB			

Product Type: RBC/Whole Blood, Plasma, Platelet, Cryo "Any" for Expired Products

WellSky Standard	Gender	Configurable?	

Expired Products: All Rule 1
 	
1. If product type = any; and
2. Unit is expired at date (and time, if applicable) of Issue (on Safety Check); then
3. Apply a safety check for a **SOFT STOP**.
   a) **Message:** "Expired product requires an override."
   b) **Reasons for override** (in this order, respectively): Medical direction, MTP SOP, No alternative unit available
	Male, Female, Unknown	**Yes**
		
		Standard is soft stop. Configurable is hard stop. All other variables besides hard/soft stop are the same.
			All Rule 2
			
			1. If product type = any; and
			2. Unit is expired at date (and time, if applicable) of Issue (on Safety Check); then
			3. Apply a safety check for a **HARD STOP**.
			   a) **Message:** "Expired product not suitable. Remove unit."

CONCLUSIONS:

WellSky Corporation concludes that WellSky™ Blood – Emergency Issue 2020 R1 is substantially equivalent to the parent device listed in that it has the similar intended use and similar technological characteristics. Testing was conducted as required by WellSky's Design Control Verification and Validation processes to evaluate the accessory and ensure the technological characteristics do not create additional questions relating to safety and effectiveness of the parent device. The results of this testing demonstrate that WellSky™ Blood – Emergency Issue 2020 R1 performs as expected and that the functional capabilities do not affect safety or effectiveness.