

Section 5.0: Premarket Notification 510(k) Summary

Sunquest Transfusion Manager™ Version 3.0; BK210556

In accordance with 21 CFR 807.92(a)

General Submission Information

Date Prepared	11-February-2021; 20-March-2021; 12-April-2021
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General Product Information

Name of Device	Sunquest Transfusion Manager
Software Version	Version 3.0
Common Name	Sunquest Transfusion Manager
Product Code	MMH
Classification Name	Blood Establishment Computer Software and Accessories
Regulatory Class	Class II General Controls and Special Controls; without exemptions
Predicate Device	Sunquest Transfusion Manager Version 2.0

Please note that Sunquest Transfusion is not an in vitro diagnostic device per the definition provided in 21 CFR 809.3, but is classified as blood establishment computer software (BECS), pursuant to 21 CFR 864.9165.

Statement of Intended Use	<p>Transfusion Manager is a comprehensive software application intended for use by trained healthcare professionals responsible for transfusion services. Transfusion Manager helps users manage the following transfusion service activities:</p> <ul style="list-style-type: none"> • Positively identify transfusion recipients. • Match blood products to recipients. • Record recipient pertinent transfusion information. • Record recipient transfusion reactions and caregiver comments.
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Detailed Product Information

<p>Device Description</p>	<p>Sunquest Transfusion Manager helps improve patient safety by guiding nurses during error-prone activities so patients receive the correct blood on every transfusion. Used by nurses in leading health systems nationwide, Sunquest Transfusion Manager optimizes patient safety and efficiency for bedside transfusions by using barcode technology to validate a unique match between the blood and the patient.</p>		
<p>Enhancement / Defect</p>	<p>Description</p>	<p>Related CR Number</p>	<p>Explanation</p>
<p>Defect</p>	<p>The Transfusion Manager application now allows to enter the actual time when the vitals were drawn which may be earlier than the current time (displayed by the system).</p>	<p>CR20-00189176</p>	<p>Bug fix - TRM allows the user to enter a time for the pre-transfusion vitals which may be earlier than the current system time and will display those vitals upon accessing the unit in TRM.</p>
<p>Enhancement</p>	<p>Transfusion Manager can now process 2D barcodes on the Patient ID screen and Unit Tag Verification screen.</p>	<p>CR20-00189094.</p>	<p>ENHANCEMENT - 2D Barcodes are now supported and TRM can process 2D barcodes correctly on the Patient ID field and Unit Tag Verification field. Users can also apply regular expressions and TRM correctly strips off the additional characters upon scan.</p>

	<p>Enhancement</p>	<p>The User Interface for Transfusion Manager is being updated from older Windows Forms to the Windows Presentation Foundation to support a more modern and intuitive User Interface.</p>	<p>includes CR09-00169697, CR15-00182487</p>	<p>ENHANCEMENT - (CR-00169697) Bundled in with User Interface improvements; related to ability to login to application with the Lab logins that have mixed case characters. (CR15-00182487) Display a warning message per date/time verification if the user enters a transfusion start date earlier than the issue date of the unit. (Other) Update screens and workflows to modern counterparts for more intuitive workflows that continue to support positive patient identification and unit verification. See screen mock-ups for the visual changes. 005 Section 5.0-a- Screen Mock Ups Examples are: removing the tree structure for patient demographics and unit information to patient demographics panel and a unit</p>
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				<p>information card; having patient confirmation after patient scanning but before display of issued units.</p>
	<p>Enhancement</p>	<p>The Transfusion Manager application now supports ISBT 128 Product Codes beyond E9999.</p>	<p>CR20-00189262</p>	<p>ENHANCEMENT - TRM now supports ISBT 128 Product Codes beyond E9999. This is an add-on support at Lab10.0 in dealing with EAnnn codes along with current Ennnn codes.</p>
	<p>Defect</p>	<p>TRM now works smoothly even if the number of ISBT 128 codes defined in the Lab Global are more than 1000.</p>	<p>CR20-00189339</p>	<p>Bug fix - TRM now works smoothly even if the number of ISBT 128 codes defined in the Lab Global are more than 1000. (fix ported from TRM 2.2 patch)</p>
<p>Performance Data</p>	<p>(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence; Testing of Transfusion Manager 3.0 included: <u>Verification</u></p> <ul style="list-style-type: none"> • Unit & Integration 			

	<ul style="list-style-type: none">• Compatibility• Functional• Performance• Regression• Security• Ignition/Installation <p><u>Validation</u></p> <ul style="list-style-type: none">• Useability <p>(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence.</p> <p>No tests were performed in the context of clinical trials.</p> <p>(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in in the General Product information section, above.</p> <p>The design control activities have been performed to ensure that safety and performance are substantially equivalent to the predicate device. Sunquest Transfusion Manager, Version 3.0 software was developed and validated using established procedures for software development. Based on the verification and validation activities performed, Sunquest Transfusion Manager software has been demonstrated to be safe and effective when utilized within its intended use.</p>
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