510(k) SUMMARY

Epic's Blood Product Administration Module Version 2-2017

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Date Prepared: 3/24/2017

Trade Name: Blood Product Administration Module Version 2-2017

Common Name: Blood Bank Software, Standalone Products

Classification: Unclassified (Software, Stand Alone Products)

Predicate Device: Blood Product Administration Module Version 0.9 (BK130037)

Intended Use / Indications for Use

The Blood Product Administration Module is a software module intended for use by healthcare professionals to assist in the identification of patients and blood products for transfusion.

The Module is based on a modular design allowing it to be used with a host electronic health record system. The Module can, through use of barcode technology, assist healthcare professionals in verifying patient identity at the bedside. The Module receives and manages information from orders placed from a host system and blood product information from an external blood bank system. The Module incorporates system-controlled logic that can require a positive match of the patient, the blood product to be administered, and information received from the external blood bank system. The Module can also check a blood product's documented expiration date for appropriateness. Blood administration information entered in the Module is transmitted to the host system for storage.

Device Description

The Blood Product Administration Module Version 2-2017 (the "BPAM 2-2017") is a software module that can assist clinicians in matching patients with ordered blood products. BPAM 2-2017 receives and manages information from orders placed from an electronic health record system (a "Host System") and blood product information from an external blood bank system. In addition, BPAM 2-2017 sends blood product administration information to the Host System for storage. BPAM 2-2017 incorporates

system-controlled logic that can require a positive match between a patient's blood product order, identification information (e.g., a barcode on the patient's identification wristband) for a patient, and identification information (e.g., barcodes on the blood product) for a blood product to be administered to the patient. BPAM 2-2017 also can check the expiration date identified on the blood product for appropriateness.

Healthcare organizations can choose whether to enable BPAM 2-2017's blood product matching functionality, or use BPAM 2-2017 without its matching functionality (e.g., to use only the BPAM 2-2017's documentation workflow). These options allow healthcare organizations that implement BPAM 2-2017 to choose the blood administration and matching workflows that work best in their clinical environments.

Although BPAM 2-2017 can display user-facing messages, which may help inform a clinician of potential safety concerns (e.g., the blood product to be administered not matching the relevant order, or the blood product being expired), the clinician can also manually verify that he is administering the intended blood product and that the blood product has not expired. BPAM 2-2017 is not intended to serve as a substitute for a clinician's professional judgment and decision making, and a clinician should not delay a needed blood transfusion because of documentation or software workflow issues.

BPAM 2-2017's functionality is designed to be used in a client/server environment on a workstation (e.g., a desktop, laptop, or tablet computer) or a mobile device, and can be used with or without barcode scanning technology. BPAM 2-2017 supports Android devices as well as Apple iOS devices.

Information from the external blood bank system is transmitted to BPAM 2-2017 via an HL-7 interface. This information can be compared and combined with information entered into BPAM 2-2017, which may include a blood product's unit number, registration number, product code, blood type, and expiration date from an ISBT-128 or ABC Codabar blood product label. Once the combined information has been collected and validated by the clinician, it is transmitted to the Host System for storage.

Performance Summary

Like the Predicate Device, BPAM 2-2017 was designed, developed, and is maintained using established software lifecycle procedures, from design through testing and product release, including updates and change control. Verification and validation testing, including design validation, unit testing, integration testing, regression testing, and user site testing, were performed to ensure that BPAM 2-2017's requirements are met. The assessment of this non-clinical testing is that the software requirements have been met and that BPAM 2-2017 functions as intended.

Verification testing took place at Epic, where mock hospital information systems were set up to serve as the test Host Systems and to test the interface functionality of receiving HL-7 interface messages from an external blood bank system. Test cases traceable to the requirements were run. The results of this testing demonstrated that the requirements have been met and BPAM 2-2017 functions as expected.

In user site testing, nurses evaluated the usability of the user interface for BPAM 2-2017 in simulated representative tasks. The results of this user site testing also demonstrated that BPAM 2-2017 functions as expected.

Regression testing confirmed that BPAM 2-2017 meets its requirements and functions as expected.

The conclusion drawn from Epic's testing of BPAM 2-2017 is that the device functions as intended and results observed were as expected.

Substantial Equivalence

The BPAM 2-2017 has the same intended use compared to the Predicate Device. In addition, the two products have very similar technological characteristics. The purpose of this submission is to describe certain minor modifications associated with additional barcode support; support for Android mobile devices; optional configuration to provide flexibility to healthcare organizations; new and modified user-facing messages; as well as minor product enhancements and labeling updates.

The following table outlines the technological characteristics of BPAM 2-2017 and the Predicate Device.

Table 24: Technological Characteristics Comparison

	BPAM 2-2017	**Predicate Device**
Communication with External Systems	Receives information from an external blood bank system via an HL-7 interface and order information from a Host System; communicates blood administration documentation to the Host System (an electronic health record system) for storage.	SAME
Blood Product Administration	Patient and blood product matching functionality; expiration date checking functionality. Incorporates system-controlled logic that can require a positive scan of a patient and a blood product and compares that information against information received from the external	SAME, except that the expired blood product warning was always overridable.

	blood bank system. Expired blood product warning may be configured to be overridable or non-overridable.	
Accessories	Designed to be used with an external blood bank system and a Host System (an electronic health record system). Currently limited for use with the 2017 version of Epic's electronic health records software. Designed to be used with a barcode scanner as an optional accessory.	SAME, except limited for use with the 2012 version of Epic's electronic health records software.
Hardware	Mobile device (Apple and Android), server, and workstation (e.g., desktop, laptop or tablet computer).	SAME, except mobile devices limited to Apple.
Barcode Types	ISBT-Compound ("2D") barcodes, ISBT-128 and Codabar barcodes. Supports ISBT-128 product codes with prefixes A-D, E, F, N (Netherlands-specific), and plasma derivatives labeled X0001000-0999000.	ISBT-128 and Codabar barcodes. Supports ISBT-128 product codes with prefixes E and F.

BPAM 2-2017 has identical or similar technological characteristics to those of the Predicate Device. No new safety or effectiveness issues are introduced, and the device's fundamental scientific technology is unchanged. Based on the comparison of the technological characteristics, BPAM 2-2017 is substantially equivalent to the Predicate Device.