510(k) SUMMARY

Epic's Blood Product Administration Module Version 4-2023

Contact Person: Brian Jacobson
Phone: (608) 271-9000
Fax: (608) 271-7237

Date Prepared: 08/08/2024

Trade Name: Blood Product Administration Module Version 4-2023

Common Name: Blood Bank Software, Standalone Products

Classification Regulation: 21 CFR 864.9165 – Blood Establishment Computer Software and Accessories

Classification: Class II

Product Code: MMH

Predicate Device: Blood Product Administration Module Version 3-2020 (BK200482)

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 product and order information from a host system and a blood bank. The Module incorporates system-controlled logic that can require a positive match of the patient, the product to be administered, and information from the blood bank. The Module can also check a product's documented expiration date for appropriateness. Administration information entered in the Module is transmitted to the host system for storage.

Device Description

The Blood Product Administration Module Version 4-2023 ("BPAM 4-2023") is a software module that can assist clinicians in matching patients with ordered blood products. BPAM 4-2023 receives and manages product and order information from an electronic health

record system (a “Host System”) and a blood bank. In addition, BPAM 4-2023 sends product administration information to the Host System for storage. BPAM 4-2023 incorporates system-controlled logic that can require a positive match between a patient’s product order, identification information (e.g., a barcode on the patient’s identification wristband) for a patient, and identification information (e.g., barcodes on a blood product) for a product to be administered to the patient. BPAM 4-2023 also can check the expiration date identified on the product for appropriateness.

Healthcare organizations can choose whether to enable BPAM 4-2023’s product matching functionality or use BPAM 4-2023 without its matching functionality (e.g., to use only the BPAM 4-2023’s documentation workflow). Healthcare organizations that enable BPAM 4-2023’s matching functionality can also choose to enable BPAM 4-2023’s flexible matching functionality for massive transfusion protocols (MTP) and similar emergency protocols. These options allow healthcare organizations that implement BPAM 4-2023 to choose the administration and matching workflows that work best in their clinical environments.

Although BPAM 4-2023 can display user-facing messages that may help inform a clinician of certain potential safety concerns (e.g., the product to be administered not matching the relevant order, or the product being expired), the clinician can also manually verify that he is administering the intended product, and that the product has not expired. BPAM 4-2023 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 transfusion because of documentation or software workflow issues.

BPAM 4-2023’s functionality is designed to be used on a workstation (e.g., a desktop, laptop, or tablet computer) or an Android or Apple iOS mobile device and can be used with or without barcode scanning technology.

Information from the blood bank can be compared and combined with information entered into BPAM 4-2023, which may include a product’s unit number, registration number, product code, blood type, and expiration date from an ISBT-128 or ABC Codabar 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 4-2023 was designed, developed, and is maintained using well-established methods from Epic’s 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 human factors/usability testing, were performed to ensure that BPAM 4-2023‘s requirements are met. The assessment of this non-clinical testing is that the software requirements have been met and that BPAM 4-2023 functions as intended.

Verification testing took place at Epic, where mock hospital information systems were set up to serve as the test Host System. Test cases traceable to the requirements were run.

The results of this testing demonstrated that the requirements have been met and BPAM 4-2023 functions as expected.

Verification and validation testing confirmed that BPAM 4-2023 meets its requirements and functions as expected.

The conclusion drawn from Epic's testing of BPAM 4-2023 is that the device functions as intended and results observed were as expected.

Substantial Equivalence

BPAM 4-2023 and the Predicate Device have the same general intended use. Although minor wording changes have been made for clarity, those minor differences do not change the intended therapeutic effect of BPAM 4-2023 as compared to the Predicate Device. The wording of the indications for use statement has been minorly updated to reflect minor editorial modifications and clarifications regarding the scope of the device. Those updates do not represent significant differences in functionality and do not raise different questions of safety or effectiveness.

In addition, the two products have very similar technological characteristics. The purpose of this submission is to describe certain modifications associated with: flexible matching functionality for use in massive transfusion protocols (MTP) and similar emergency protocols; modified user-facing messages; fixes to unresolved anomalies; labeling for use with additional hardware and off-the-shelf software; support for ISBT-128 product codes beginning with S; and updated labeling to make the device easier to configure and use.

The following table outlines the technological characteristics of BPAM 4-2023 and the Predicate Device.

Table 1: Technological Characteristics Comparison

	BPAM 4-2023	Predicate Device
Communication with External Systems	Receives information from a blood bank system and a Host System (an electronic health record system); communicates administration documentation to the Host System for storage.	SAME
Product Administration	Patient and product matching functionality; expiration date checking functionality. Incorporates system-controlled logic that can require a positive scan of a patient and a product and compares that information	SAME

	against information from the external system.	
Technological Makeup	Software-only device.	SAME
Environment	The clinician can use the device in a client/server environment on a workstation (e.g., a desktop, laptop, or tablet computer) and/or Apple iOS or Android device	SAME
Accessories	Designed to be used with a blood bank system and a Host System (an electronic health record system). Limited for use with versions of Epic's electronic health records software beginning with the February 2024 version. Designed to be used with a barcode scanner as an optional accessory.	SAME, except limited for use with versions of Epic's electronic health records software beginning with the November 2020 version.
Hardware	Mobile device (Apple and Android), server, and workstation (e.g., desktop, laptop, or tablet computer). Barcode scanner (optional)	SAME
Barcode Types	ISBT-Compound ("2D") barcodes, ISBT-128 and Codabar barcodes. Supports ISBT-128 product codes with prefixes A-D (including those with the Belgium-specific identifier &<), E, F, N (Netherlands-specific), S, and plasma derivatives labeled X0001000-0999000.	SAME, except ISBT-128 product codes with prefix S are not supported.

BPAM 4-2023 has identical or similar technological characteristics to those of the Predicate Device. No new safety or effectiveness issues are introduced as a result of minor differences in technological characteristics, and the device's fundamental scientific technology is unchanged. Based on the comparison of the technological characteristics, BPAM 4-2023 is substantially equivalent to the Predicate Device.