

510(k) SUMMARY

Epic's Blood Product Administration Module Version 3-2020

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Trade Name: Blood Product Administration Module Version 3-2020

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 2-2017 (BK170032)

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 blood product and order information from a host system and a 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 from the 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 3-2020 (the "BPAM 3-2020") is a software module that can assist clinicians in matching patients with ordered blood products. BPAM 3-2020 receives and manages blood product and order information from

an electronic health record system (a “Host System”) and a blood bank system. In addition, BPAM 3-2020 sends blood product administration information to the Host System for storage. BPAM 3-2020 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 3-2020 also can check the expiration date identified on the blood product for appropriateness.

Healthcare organizations can choose whether to enable BPAM 3-2020’s blood product matching functionality, or use BPAM 3-2020 without its matching functionality (e.g., to use only the BPAM 3-2020’s documentation workflow). These options allow healthcare organizations that implement BPAM 3-2020 to choose the blood administration and matching workflows that work best in their clinical environments.

Although BPAM 3-2020 can display user-facing messages, which may help inform a clinician of certain 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 3-2020 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 3-2020’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 system can be compared and combined with information entered into BPAM 3-2020, 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 3-2020 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 3-2020’s requirements are met. The assessment of this non-clinical testing is that the software requirements have been met and that BPAM 3-2020 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 3-2020 functions as expected.

Verification and validation testing confirmed that BPAM 3-2020 meets its requirements and functions as expected.

The conclusion drawn from Epic’s testing of BPAM 3-2020 is that the device functions as intended and results observed were as expected.

Substantial Equivalence

The BPAM 3-2020’s intended use is the same as the intended use of 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 introduce a new intended use or 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: a revision to the software code infrastructure and architecture; support for scanning additional blood product barcode variations; minor aesthetic changes; minor code changes to account for variation in Host System functionality; minor code changes for ease of internal development tracking and coding conventions; modified user-facing messages; fixes to unresolved anomalies; labeling for use with additional hardware and off-the-shelf software; and updated labeling to make the device easier to configure and use.

The following table outlines the technological characteristics of BPAM 3-2020 and the Predicate Device.

Table 1: Technological Characteristics Comparison

	BPAM 3-2020	Predicate Device
Communication with External Systems	Receives blood product and order information from a Host System and blood bank 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	SAME

	information against information from the blood bank system.	
Technological Makeup	Software-only device.	SAME, except with different software code infrastructure and architecture.
Accessories	<p>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 August 2020 version.</p> <p>Designed to be used with a barcode scanner as an optional accessory.</p>	SAME, except limited for use with versions of Epic's electronic health records software beginning with the Epic 2017 version.
Hardware	Mobile device (Apple and Android), server, and workstation (e.g., desktop, laptop, or tablet computer).	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), and plasma derivatives labeled X0001000-0999000.	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.

BPAM 3-2020 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 3-2020 is substantially equivalent to the Predicate Device.