510(k) Summary

Contact Details

Applicant Name:	Buoy Software, LLC
Applicant Address	811 Barton Springs Road, Suite 510 Austin TX 78704 United States
Applicant Contact Telephone:	513-314-4653
Applicant Contact:	Mrs. Christina Miracle
Applicant Contact Email:	christina@buoysoftware.com

Device Name

Device Trade Name:	Blood Product Questionnaire Module (v2.0.0)
Common Name:	Blood establishment computer software and accessories
Classification Name:	Blood Establishment Computer Software And Accessories
Regulation Number:	864.9165
Product Code:	MMH

Legally Marketed Predicate Device(s)

Predicate #:	BK231004
Predicate Trade Name:	Blood Product Questionnaire Module (v1.0.0)
Product Code:	MMH

Device Description Summary

The Blood Product Questionnaire Module is a Software as a Medical Device (SaMD) intended to support single and/or multi-site blood establishment collection facilities to create and/or manage a Donor History Questionnaire (DHQ), collect and/or review

donor history information, determine visit requirements, determine donor eligibility, and unit suitability as determined through system logic or trained facility staff interpretation.

The device functions as a deterministic, rules-based evaluation system in which qualified facility staff define the decision criteria governing eligibility, suitability, and related quality determinations. The device evaluates structured inputs including clinical questionnaire responses, laboratory test results, and operational data against those staff-configured criteria to produce structured outputs, including eligibility and suitability determinations, deferral records, unit status assignments, lookback initiations, and operational readiness flags. All device outputs are produced through rule-based logic consistent with the facility's standard operating procedures.

The device is deployed as a secure, cloud-based software application accessed through industry standard computers and mobile devices at blood establishment collection facilities. It is intended for use by trained blood establishment collection facility staff or by blood donors.

Features Cleared Under Predicate Submission (BK231004)

BPQM v2.0 retains the following features previously cleared under BK231004:

- Configure Donor History Questionnaire: Trained facility staff configure a DHQ covering general health information.
- Collection of Donor History Information: Donors authenticate their identity and complete the DHQ via a web application. The SaMD verifies the donor’s donation status.
- Determine Visit Requirements: The SaMD determines the visit requirements a donor must fulfill as part of their donation.
- Donor Evaluation Process: After DHQ completion, the SaMD evaluates donor responses against configured eligibility criteria.

New Features Introduced in BPQM v2.0

BPQM v2.0 introduces four new features within the Helm module.

- Test Result Configuration: Trained staff configure the actions the SaMD will perform when specific test panel results are received, in accordance with the blood establishment’s standard operating procedures.
- Test Result Evaluation / Assessment of Blood Product Suitability: When test panel results are received from a laboratory, the SaMD evaluates whether the results are acceptable or unacceptable and automatically applies the actions configured by trained staff.
- Equipment Readiness Configuration: Designated staff define equipment readiness requirements within the SaMD.

- Equipment Readiness: The Equipment Readiness feature ensures that all medical equipment involved in the collection of blood products is regularly assessed and verified as functional, safe, and ready for use.

Intended Use/Indications for Use

The Blood Product Questionnaire Module supports single and/or multi-site blood establishment collection facilities' creation of a donor history questionnaire, the collection of donor history, the determination of visit requirements, the determination of donor eligibility, and unit suitability as determined through system logic or via analysis by trained facility staff members.

Indications for Use Comparison

Both the subject device and the predicate device are blood establishment computer software intended to document, query, and access integrated information pertaining to blood product.

The subject device offers additional functionality and indications as compared to the predicate device. Specifically, the subject device includes unit suitability.

This new indication is accomplished using the same technological elements and the difference does not raise different questions of safety and effectiveness.

Technological Comparison

While there are minor differences in technological characteristics between the proposed device and its predicate device related to the test results and equipment readiness features, none of these differences raise new types of safety or effectiveness questions. The equivalent differences are as follows:

- The subject device supports the newest operating system versions.
- The subject device supports the newest browser versions released within the last year.

Non-Clinical and/or Clinical Tests Summary & Conclusions

The subject device meets the applicable requirements of ANSI/AAMI/IEC 62304:2006 & A1: 2016 Medical device software— Software life cycle processes. Software testing was performed at the unit, integration, and system levels as well as human factors and usability testing. All applicable requirements were met.

Testing for the Blood Product Questionnaire Module v2.0 verified the system is safe and effective and performs as well or better than the predicate device when utilized within its intended use.