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510(k) Summary

Contact Details

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Device Name

Device Trade Name:	Blood Product Questionnaire Module
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 #:	BK210607
Predicate Trade Name:	SoftDonor Version 4.5.5
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, and determine donor eligibility through system logic or trained facility staff interpretation.

Configure Donor History Questionnaire
Trained facility staff are able to configure a DHQ, which covers general health information,

history of infectious diseases, lifestyle/behavioral factors, travel history, medical conditions, and other criteria to assess the donor's eligibility for donation.

Collection of Donor History Information
Donors use a native iPad application to authenticate their identity, answer questions, and confirm receipt of blood product donor/donation education materials.

The SaMD determines if a donor is eligible to take a DHQ by ensuring the donor does not have an active deferral or is in violation of the establishment's donation frequency rules.

A deferral refers to the temporary or permanent prevention of donation due to certain conditions or circumstances.

Donation frequency rules refer to how often a donor can donate.

If a donor is eligible to take a DHQ, the donor completes the DHQ and provides 'Yes', 'No', or 'I Don't Know' responses to all of the questions.

The application allows the donor to exit at any point and will only store and manage donor data for a completed DHQ. The DHQ provides step-by-step prompts to guide the donor through the process.

Determine Visit Requirements
The SaMD also provides the visit requirements a donor must complete as a part of their donation. In addition to completing a DHQ, this includes but is not limited to determining when donors are required to provide a specific test or set of tests and to receive a physical with trained facility staff.

Donor Evaluation Process
After the donor completes the DHQ, the next steps of the evaluation depend on the status of the responses provided by the donor. Either the responses are acceptable, and the donor is eligible to donate, or the answers are reviewed by trained facility staff and the SaMD uses the trained staff's responses to determine if the donor is eligible to donate on that day.

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, and the determination of donor eligibility through system logic or via analysis by trained facility staff members.

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Indications for Use Comparison

Both the subject device and the predicate device are intended for use in blood establishment collection facilities, whether single-site or multi-site. Both devices are specifically intended to assist knowledgeable, trained staff in the process of documenting, querying, and accessing integrated information pertaining to blood donors.

The predicate device, SoftDonor Version 4.5.5, offers additional functionality and indications as compared to the subject device. For example, the predicate device is capable of capturing various steps and events, encompassing the manufacturing of blood and blood components, and authorizing the release of products for transfusion purposes. The subject device solely focuses on determining the eligibility of donors to donate. In other words, the subject device's indications for use are a subset of the predicate device's indications, as the latter encompasses additional functionality.

In summary, both devices have the same intended use and similar indications for use. They both support the incorporation of user or donor-administered history questionnaire functionality, accompanied by system logic for determining donor eligibility.

Technological Comparison

The subject device and the predicate device have equivalent technological characteristics:

-Both the subject device and the predicate device are web-based.

-Both the subject device and the predicate device use industry standard operating systems.

-Both the subject device and the predicate device use industry standard browsers / Applications.

-Both the subject device and the predicate device use industry standard computing equipment.

-Both the subject device and the predicate device support the English language.

-Both the subject device and the predicate device can adjust the font / size on the hardware.

The differences between the subject device and the predicate device do not raise different questions of safety and effectiveness, and are listed below:

-The subject device solely focuses on determining the eligibility of donors to donate. The

predicate device offers additional functionality. Specifically, the predicate device includes component production, inventory control, and inventory distribution.

-The subject device does not utilize peripheral hardware as its output is to another application. The predicate device utilizes peripheral hardware to support the additional functionalities.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Software verification and validation testing as well as human factors and usability testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Clinical tests are not applicable to the device.

The software verification and validation testing verified that the design requirements were successfully met. The Intended use and user needs were successfully validated.