510(k) Summary

DATE SUBMITTED

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SUBMITTER

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DEVICE INFORMATION

Trade Name of Device: Lookback Notification System version 2.0
Regulation: 864.9165
Product Classification: Blood Establishment Computer Software and Accessories
Device Classification: Class II (special controls)
Product Code: MMH

LEGALLY MARKETED PREDICATE DEVICE

Trade Name of Device: Lookback Notification System version 1.0
Relevant 510(k) Number: BK150347
Product Code: MMH
Manufacturer and 510(k) holder: BioLife Plasma Services L.P.

DEVICE DESCRIPTION SUMMARY

The Lookback Notification System version 2.0, hereafter referred to as LNS, is an internal Software as a Service (SAAS) cloud-based software application hosted on Salesforce. LNS is intended to generate and maintain electronic lookback records and allows for the automated creation, distribution, and updating of applicable consignee notifications to assist in effectively identifying and removing unsuitable product units (Source Plasma) before manufacturing.

LNS creates and maintains electronic lookback records based on post-donation information, manufacturing errors, positive test results data, and brokered plasma information, either electronically or manually entered. In addition, LNS allows the automated creation, distribution, and updating of applicable lookback consignee notifications.

INTENDED USE

The Lookback Notification System is intended to generate and maintain electronic lookback records and allows for the automated creation, distribution and updating of applicable consignee

notifications to assist in effectively identifying and removing unsuitable units (Source Plasma), prior to manufacturing.

INTENDED USE COMPARISON

The Intended Use for the Lookback Notification System version 2.0, hereafter referred to as LNS, differs from the predicate device, the Lookback Notification System v 1.0. The intended use was updated for clarity. No new functionality has been added to the product that would change the intended use of the device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Characteristics	Predicate Device: LNS version 1.0	Subject Device: LNS version 2.0
Environment of Use	LNS is a computer system used in an office environment at BioLife Plasma Services corporate headquarters in Northern Illinois.	LNS is a computer system used in an office environment at BioLife Plasma Services corporate headquarters in Northern Illinois and the BioLife Plasma Services centers.
Intended Users	Regulatory Affairs and Lookback Department	Regulatory Affairs, Lookback, Center, and QA.
Interfaces	Automated Plasma Dispositioning System (APDS)	Automated Plasma Dispositioning System (APDS) via Informatica Donor Information System (DIS) via Operational Data Store (ODS) Database (DB) via Informatica or MuleSoft
Local Area Network	**Desktop/WorkStation:** Isolated network	**Desktop/Laptop (wired network):** Isolated network **Salesforce (Wi-Fi):** Network latency of 150 ms or less and download speed of 3Mbps or greater.
Operating System	Microsoft Windows 7	Company-managed workstation using company-supported

Characteristics	Predicate Device: LNS version 1.0	Subject Device: LNS version 2.0
		operating systems with access to the latest version of Google Chrome
Platform	Microsoft Windows environment	Salesforce SAAS (Software as a Service) based application

The differences in the principles of operation and technology characteristics between the proposed LNS software device and the predicate device do not raise new questions of safety or effectiveness.

COMPARISON OF FUNCTIONAL CHARACTERISTICS

Areas of Comparison	Predicate	Subject Device
Ability to create and maintain Post Donation Information (PDI) Lookback records	✓	✓
Ability to create and maintain Positive Test Result (PTR) Lookback records	✓	✓
Ability to create and maintain non-conformance (NCR) Lookback records	✓	✓
Ability to create and maintain Brokered Plasma (BP) Lookback records	✓	✓
BPDR Assessments	✓	✓
Requests for Clarification and/or Additional Documentation (ReCADs)	✓	✓
UDR, Lab Results, and Lab Deferrals Positive/Reactive Reports	✓	✓
Assessment Codes	✓	✓
Consignee notifications	✓	✓

NON-CLINICAL AND/OR CLINICAL TESTS

The following non-clinical testing was provided in support of the substantial equivalence determination:

- Cybersecurity
- Software Verification and Validation
- Function Performance Testing (Bench)

Cybersecurity

All identified cybersecurity risks were sufficiently mitigated to a controlled state by using the cybersecurity controls designed and implemented by BioLife.

Software Verification and Validation

Software verification and validation testing was performance in accordance with the FDA Guidance, *General Principles of Software Validation*. The system complies with ANSI AAMI IEC 62304.

Function Performance Testing (Bench)

Bench verification testing for LNS consisted of performance and usability/human factors testing. The testing demonstrated that LNS will perform consistently at standard and high capacities with no delays and is safe and effective for the intended users, uses, and use environments.

SUMMARY AND CONCLUSIONS

Based upon the comparison of the labeling and the technological and functional characteristics, the information provided in this submission – including results from risk assessments and testing activities related to cybersecurity, verification, validation, performance, and usability/human factors – demonstrates that the proposed LNS device functions as intended and is substantially equivalent to the predicate device. Differences between the proposed and predicate devices do not raise any different questions about safety or effectiveness. Therefore, BioLife concludes that the proposed device, LNS version 2.0, is substantially equivalent to the predicate device (BK150347).