HAEMONETICS®

510(k) Summary

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Device Information

TRADE Name:	NexLynk DMS® Donor Management System
Common Name:	Blood Establishment Computer Software
Classification Name:	Blood Establishment Computer Software and Accessories
Regulation Number:	21 CFR 864.9165
Review Panel:	Hematology
Product Code:	MMH
Device Class:	2

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
BK150330	NextGen 3.0.0	MMH

Device Description Summary
The Haemonetics NexLynk DMS® Donor Management System is configurable software that automates the previously manual processes at a source plasma donation center. The software manages the donor visits, presents the donor health questionnaire and records donor answers, maintains records of the donation procedures, tracks test samples, processes test results, manages immunizing donors in specialty plasma donation programs, and manages the release and shipment of units out of the source plasma donation center for further manufacturing. The software includes safety checks to help ensure donor suitability and unit releasability requirements are met.

Intended Use
The NexLynk DMS® Donor Management System is intended for use at source plasma donation centers to determine donor eligibility for a donation, calculate donor nomograms, crossmatch immunogens for immunizing specialty plasma donors, and support product releasability for further manufacturing into therapies.

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Indications for Use

The NexLynk DMS® Donor Management System is a record management software tool and database of information for use in Source Plasma establishments. The software assists in the manufacture of Source Plasma by performing the following functions:

- Determine donor eligibility and component suitability for release
- Manage component collection, processing, testing, labeling, and storage
- Crossmatch immunogens for immunizing specialty plasma donors
- Conduct unit inventory lookbacks

The NexLynk DMS® Donor Management System is not indicated for patient management, treatment, or clinical care at a health care facility.

Indications for Use Comparison

The Indications for Use for the NexLynk DMS® Donor Management System are different from the predicate device, NextGen 3.0.0, because the indications for use were clarified. No new functionality has been added to the product that would cause a change to the indications for use. The currently cleared indications of the predicate (BK150330) continue to be supported.

Technological Comparison

There is no change to the underlying technology, or principle of operation from the predicate NextGen 3.0.0 (BK150330). The device functions with the same intended use for the electronic facilitation and management of the source plasma collection center processes. Through the discussion on substantial equivalence, the risk management documentation, and the testing provided, it is concluded that the changes associated with NexLynk DMS 4.10.0 do not change the risk-benefit profile of the NexLynk DMS® Donor Management System.

Non-Clinical and/or Clinical Tests

The non-clinical testing performed to support this premarket submission was performed in accordance with the FDA Guidance, *General Principles of Software Validation (2002)*. The software testing consisted of thorough verification and validation testing to ensure the subject device is as safe, as effective, and performed as well as or better than the predicate device.

No clinical testing was performed in support of this premarket submission for the NexLynk DMS® Donor Management System.

Summary & Conclusions

The non-clinical testing and comparison to the predicate device show the subject NexLynk DMS® Donor Management System 4.10.0 to be substantially equivalent to the predicate device and that there is no impact to the safety and effectiveness of the device.

Results from the non-clinical testing demonstrate that the NexLynk DMS® Donor Management System 4.10.0 is as safe and effective, and it performs as well as its proposed predicate device.

In conclusion, the NexLynk DMS® Donor Management System 4.10.0 is substantially equivalent to the predicate device in terms of functionality, performance, technological characteristics, and Indications for Use, including for safety and effectiveness.