510(K) SUMMARY

Date: December 20, 2000

Sponsor:
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Proprietary Name:
Haemonetics' LN832F – Two Unit Red Cells Disposable Set with Leukocyte Reduction Filter

Haemonetics MCS+ LN8150 – Automated Blood Component Collection System for Red Cell Apheresis

Classification Name:
Empty container for the collection and processing of blood and blood components (21 CFR 864.9100)

Automated Blood Cell Separator (21 CFR 864.9245)

Common Name:
LN832F Disposable Set
MCS+ LN8150 for Red Cell Apheresis

Predicate Devices:

Predicate Device	Reference
LN 832F – Two Unit Red Cells Disposable Set with Leukocyte Reduction Filter, with filtration at room temperature within 8 hours of venipuncture	BK990044

DEVICE DESCRIPTION

Modification to an Existing Device
This Special 510(k) premarket notification describes a modification to Haemonetics' currently legally marketed LN832F Disposable Set. The proposed modifications involve pre-filtration holding time and temperature to allow blood centers to store the collected RBC product for up to 72 hours after venipuncture at 1 – 6 °C, prior to leukocyte reduction of the collected RBCs using the Pall RC2H filter. **The intended use of the modified device is the same as for the predicate device and has not changed as result of the changes in pre-filtration holding time and temperature.**

Additionally, the design configuration, material composition, manufacturing methods and operational principles for the changed device are equivalent to those of the predicate device.

Intended Use
To collect, leukocyte reduce (by gravity filtration), and store two (2) units of apheresis RBCs for up to 42 days.

DESIGN CONTROL ACTIVITIES

For the production, design, manufacturing and worldwide marketing of automated blood component collection systems, Haemonetics has established and is operating under a quality system that is based upon the requirements of the US Food and Drug Administration's Quality System Regulation, International Organization for Standardization's ISO 9001, the European Committee for Standardization's EN 46001, and the Medical Device Directive 93/42/EEC.

In accordance with Haemonetics' Quality System, potential risks associated with the planned changes in pre-filtration holding time and temperature were identified. Verification testing has been performed and demonstrated that the performance of the modified device is not adversely affected by the listed changes.

CONCLUSION

The LN832F and its associated modified pre-filtration holding temperature and time is substantially equivalent to legally marketed devices. The pre-filtration holding time and temperature have been modified from Haemonetics' currently cleared gravity filtration reduction process which involves filtration of the collected RBC units at room temperature within 8 hours of venipuncture; these changes do not affect the intended use or alter the fundamental scientific technology of the device.