BK990033

Section 7
510(k) Summary

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Sponsor: Haemonetics Corporation
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Trade or Proprietary Name: Haemonetics MCS+ (LN8150)

Common or Usual Name or Classification Name: Automated blood cell separator (21 CFR 864.9245)

Predicate Device: Haemonetics MCS+ (LN8150)

DEVICE DESCRIPTION

Modification to an Existing Device
This Special 510(k) premarket notification describes a modification to Haemonetics' currently marketed MCS+ (LN8150). Currently, all collection protocols performed on the MCS+ (LN8150) use an anticoagulant to anticoagulated whole blood ratio (A/C Ratio) of 1:16. Haemonetics is submitting this Special 510(k) to permit it to modify the A/C Ratio to 1:12. The modification is a change in hardware only.

Intended Use
A device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration. This device operates on a centrifugal separation principle. The separation bowls of the centrifugal blood cells separators are disposable.

DESIGN CONTROL ACTIVITIES

For the production, design, manufacturing and worldwide marketing of 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 Union's EN 46001 and the Medical Device Directive 93/42/EEC.

In accordance with the Haemonetics' Quality System, potential risks associated with the hardware modification on the MCS+ LN8150 were identified. Verification testing has been performed and verifies that the change to the anticoagulant ratio will not decrease the quality of the blood components collected with the device.

CONCLUSION

The MCS+ LN8150 using a 1:12 A/C Ratio is substantially equivalent to a legally marketed device, the Haemonetics' MCS+ LN8150 using a 1:16 A/C Ratio.