NOV 18 1999

K993581

510(K) SUMMARY

Date: October 18, 1999

Sponsor: Haemonetics Corporation
400 Wood Road
Braintree, MA 02184

Contact: Alicia R. Lopez
Tel: (781) 356-9253
Fax: (781) 356-3558

Proprietary Name: Haemonetics LN193 Disposable Set (210 mL bowl with diverter), for use with Haemonetics Cell Saver HaemoLite 2 family of autologous blood recovery systems

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

Common Name: LN193, HaemoLite® Autotransfusion Disposable Set

Predicate Devices:

Predicate Device	Reference
LN 163 – Haemonetics Cell Saver HaemoLite 2 Disposable Set (200 mL bowl with diverter) [6]	K883934

DEVICE DESCRIPTION

Modification to an Existing Device

This Special 510(k) premarket notification describes a modification to Haemonetics' currently legally marketed autotransfusion disposable set LN163. The modifications are dimensional changes to 1) the centrifugal processing bowl, and the Final Product Bag and Waste Bag incorporated in the LN163 disposable set, and 2) the disposable thermoformed tub used for packaging of the LN163 disposable set. **The intended use of the modified disposable set (the "LN193") is the same as for the LN163 disposable set and has not changed as result of the change in centrifugal blood processing bowl.** Additionally, the design configuration, material composition, manufacturing methods and operational principles for the LN193 disposable set are equivalent to those of the LN163 disposable set.

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[6] The LN163 Disposable Set for use with the Haemonetics Cell Saver HaemoLite 2 Autologous Blood Recovery System was reviewed by FDA under K883934; the LN163 Disposable Set at that time was referred to as the LN162, and the HaemoLite 2 was referred to as the HaemoLite B.

Intended Use
Haemonetics LN193 disposable set is to be used with the Haemonetics Cell Saver HaemoLite 2 family of autologous blood recovery systems, to collect, concentrate, and wash red blood cells from diluted intraoperative and post-operative shed blood for autotransfusion.

DESIGN CONTROL ACTIVITIES
For the production, design, manufacturing and worldwide marketing of automated blood processing 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 dimensional changes were identified. Verification testing has been performed and demonstrated that the performance of the modified LN163 Disposable Set is not adversely affected by the listed changes.

CONCLUSION
The LN193 disposable set is substantially equivalent to legally marketed devices. The LN193 disposable set is a modification to Haemonetics' currently marketed LN163 disposable set; the modifications are limited to dimensional changes to the centrifugal blood processing bowl, the Final Product Bag and Waste Bag, and the disposable tyvek tub used for packaging. These changes do not affect the intended use or alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Ms. Alicia R. Lopez
Corporate Vice President and General Counsel
HAEMONETICS CORPORATION
400 Wood Road
Braintree, Massachusetts 02184-9114

Re: K993581
Autotransfusion Disposables Set
Regulatory Class:II (Two)
Product Code: CAC
Dated: October 18, 1999
Received: October 22, 1999

Dear Ms. Lopez:

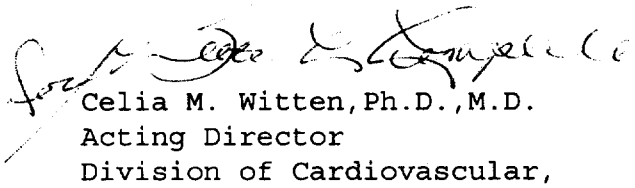
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten,Ph.D.,M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993581

2.7 Indication for Use Statement

510(k) Number: Not assigned

Device Name: Haemonetics LN193 Disposable Set (210 mL bowl with diverter), for use with Haemonetics Cell Saver HaemoLite 2 family of autologous blood recovery systems

Indications for Use: To be used with the Haemonetics Cell Saver HaemoLite 2 family of autologous blood recovery systems to collect, concentrate, and wash red blood cells from diluted intraoperative and post-operative shed blood for autotransfusion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use L OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993581