

AUG 20 1998

## 510K Summary

K982755

**Submitted by:** Medtronic Blood Management  
18501 E. Plaza Drive  
Parker, CO 80134-9061 USA

**Manufacturing Facility:** Medtronic Blood Management  
18501 E. Plaza Drive  
Parker, CO 80134-9061 USA

**Submitted Device:** Modification to existing device: This submission would allow the use of an adjustable external vacuum regulator.

Trade Name: autoLog Autotransfusion System  
Common Name: Autotransfusion Apparatus

**Device Classification:** Class II

21 CFR § 868.5830 "*Autotransfusion Apparatus*", which is identified as, "*an autotransfusion apparatus is a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma.*"

**Product Description:** The description of the device remains the same as 510k # K972894.

"The autoLog Autotransfusion System is an autotransfusion apparatus (including disposable kit). The system is a centrifugal unit that is used to collect autologous blood peri-operatively and post-operatively into a collection reservoir with an appropriate amount of anticoagulant. This autologous blood is then processed by centrifugation, separating the red cells from the plasma. Contaminating debris is subsequently washed out by the introduction of normal saline in a wash cycle. The resulting packed red cells, suspended in normal saline, are pumped to a transfer bag, and may be reinfused to the patient."

**Intended Use:** The intended use of the device has not changed from 510k # K972894. It remains as follows:

"The autoLog is intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Such areas of application may include, but are not limited to, the following:

- General, Cardiovascular, Orthopedic, Vascular, Plastic/Reconstructive, Obstetric/Gynecologic and Neurosurgical
- Postoperative treatment areas"

**Performance Standards:** Per section 514 of the Food, Drug and Cosmetics Act, there are no specific performance standards established for this device.

**Statement of Substantial Equivalence - Predicate Device:** This device is substantially equivalent to the autoLog Autotransfusion System (K972894). The modification concerns the use of an external adjustable vacuum regulator in place of the current internal non-adjustable vacuum regulator. Except for the ability to adjust the vacuum delivered to the reservoir bag, all other features, specifications, operating principles and materials of the device are identical. There are no changes that affect the biocompatibility or the sterility of the system's disposables.

**Testing:** A qualification was done to confirm that no functional differences between the predicate and the modified device exist. This testing was specific to the changes proposed.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Stephen McKelvey  
QA Project Manager  
Medtronic Blood Management  
18501 East Plaza Drive  
Parker, CO 80134-9061

Re: K982755  
autoLog Autotransfusion System  
Regulatory Class: II (Two)  
Product Code: CAC  
Dated: June 26, 1998  
Received: June 29, 1998

Dear Mr. McKelvey:

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.

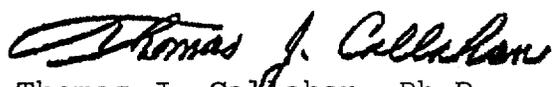
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INTENDED USE STATEMENT

510(k) Number (if known): K 98 2755

**Device Name:**

autoLog Autotransfusion System

**Indications For Use:**

The autoLog is intended for use in the collection, concentration, washing, and reinfusion of autologous blood. Such areas of application may include, but are not limited to, the following:

- General, Cardiovascular, Orthopedic, Vascular, Plastic/Reconstructive, Obstetric/Gynecologic and Neurosurgical
- Postoperative treatment areas

The intended use of this premarket notification has not changed from the autoLog 510(k) - K972894.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Seena G. Gumber*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K 98 2755

Prescriptive Use

OR

Over-the-Counter Use