AUG 1 2 2002 K021902

Appendix II

510(k) Summary
Magellan™ Autologous Platelet Separator System
(as required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	Medtronic Perfusion Systems
Address:	7611 Northland Drive N Minneapolis, Minnesota 55428-1088 U.S.A.
Telephone Number:	763.391.9000
Contact Person:	Lucy Tan
Date Submission Prepared:	June 07, 2002

B. Device Information

Device Trade Name:	Magellan™ Autologous Platelet Separator System
Common or usual Name:	General Purpose Centrifuge for Clinical Use
Classification Name:	General purpose laboratory equipment labeled or promoted for a specific medical use (21 CFR 862.2050)
Predicate Device:	SmartPReP™ Centrifuge System Harvest Technologies Corp. K991430 – 05/28/1999
Device Description:	Magellan Autologous Platelet Separator system consists of a microprocessor controlled table-top centrifuge and processing disposables designed to allow for safe and rapid automatic separation of plasma and platelets. The centrifuge spins at a maximum speed of 3800 rpms at the maximum g-force of approximately 1300g.
Indications for Use:	The Magellan Autologous Platelet Separator System is designed to be used in the clinical laboratory or intraoperatively at point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood.

C. Comparison of Required Technological Characteristics

The technological characteristics of the Magellan Platelet Separator system are substantially equivalent to the noted predicate device.

D. Performance Data

Performance data that supports the safety and effectiveness of the use of Magellan Autologous Platelet Separator System is included in this 510(k) premarket notification.

D. Conclusion

Magellan Autologous Platelet Separator System is substantially equivalent to the noted predicate device based on the similarities of technological characteristics, the identical indications for use and the results of performance comparative testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 2 2002

Ms. Lucy Tan
Senior Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive N.
Minneapolis, Minnesota 55428-1088

Re: k021902
Trade/Device Name: Magellan™ Autologous Platelet Separator System
Regulation Number: 21 CFR § 862.2050
Regulation Name: General purpose laboratory equipment labeled or promoted for a specific medical use
Regulatory Class: II
Product Code: FMF, JQC
Dated: June 7, 2002
Received: June 10, 2002

Dear Ms. Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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) 594-4588. 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 International and Consumer 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix III
Indications for Use Statement

510(k) Number (if known): K021902

Device Name: Magellan™ Autologous Platelet Separator System

Indications for Use:

The ***Magellan™ Autologous Platelet Separator System*** is designed to be used in the clinical laboratory or intraoperatively at point-of-care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood. The plasma and concentrated platelets produced can be used for diagnostic tests.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021902

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)