K020147

Appendix II

APR 0 3 2002

510(k) Summary

(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:	January 15, 2002

B. Device Information

Common or usual Name:	Syringe
Classification Name:	Piston Syringe
Predicate Device:	1) Surgical Sealant Applicator, Micromedics, Inc K883338 – 8/23/1988 2) Harvest Technologies Dual Liquid Applicator, Harvest Technologies K000456 – 6/1/2000
Device Description:	The Magellan Ratio Dispenser Kit consists of the following components: ▪ 12 cc legally marketed disposable piston syringe ▪ 1 cc legally marketed disposable piston syringe ▪ Dispenser Handle ▪ Plunger clip ▪ Dual channel tip (spray or cannula) ▪ Two medicine cups
Indications for Use:	The Magellan Ratio Dispenser kit is intended to assist the user in simultaneously delivery two non-homogeneous liquids to the same treatment area(s).

C. Comparison of Required Technological Characteristics

The technological characteristics of the Magellan™ Ratio Dispenser Kit are substantially equivalent to the predicate device including product design, materials, packaging, and sterilization.

D. Performance Data

Performance data that supports the safety and Effectiveness of the use of Magellan Ratio Dispenser Kit is included in the submission.

D. Conclusion

Medtronic Perfusion Systems considers the Magellan Ratio Dispenser Kit to be substantially equivalent to the noted predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lucy Tan
Senior Product Regulations Manager
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, Minnesota 55428

APR 0 3 2002

Re: K020147
Trade/Device Name: Magellan™ Ratio Dispenser Kit
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 15, 2002
Received: January 16, 2002

Dear Ms. Tan:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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"(21 CFR 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020147

Device Name: Magellan™ Ratio Dispenser Kit

Indications for Use:

The Medtronic Magellan™ Ratio Dispenser Kit including tip is intended to assist the user in simultaneously delivering two non-homogenous liquids to the same treatment area(s).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Roberto Cucento
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020147