DEC 2 9 1999

K983250

510(k) Summary

Summary of Safety and Effectiveness

Submitter:	MR Equipment Corporation
Address:	6 Washington Avenue Bay Shore, NY, 11706
Telephone:	(516) 243-3500
Contact:	President
Prepared:	December 15, 1997
Proprietary Name:	Invasive Blood Pressure function for Model 9500 Multigas Monitor
Common/Classification Name:	Invasive Blood Pressure function
Predicate Devices:	BCI Model 9100 Multigas Monitor with Invasive Blood Pressure function

New Device Description:

The Invasive Blood Pressure function is an addition to a device legally marketed by MR Equipment Corporation. The device provides an additional measurement function to the Model 9500 Multigas Monitor. The existing 9500 monitor has pulse oximetry, ECG, non-invasive blood pressure (NIBP), capnograph and, optionally, oxygen and agent gas measurement functions. The Model 9500 is based on the BCI Model 9100 monitor with the same measuring functions, but the Model 9500 is specifically intended for use in the MR environment.

Intended Use

The Invasive Blood Pressure function provides for two isolated channels of invasive blood pressure measurement in the MR imaging environment. The IBO function is an optional module for the Model 9500. When active, the Invasive Pressure display shows the label chosen, systolic pressure and (optionally) its high alarm limit, diastolic pressure and (optionally) its low alarm limit, and the mean pressure. Waveforms may be displayed, and trend data collected for long term monitoring.

Performance Testing:

The Model 9500 Multigas monitor meets IEC 601-1, IEC 601-1-2, IEC 801-2, -3, -4, -5, CISPR 11. In addition, tests were performed to establish that the Model 9500 operated in the MRI environment substantially equivalent to the predicate device.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 1999

G. Ronald Morris, Ph.D.
Magnetic Resonance Equipment Corporation
6 Washington Avenue
P.O. Box 5489
Bay Shore, NY 11706

Re: K983250
Model 9500 Multigas Monitor
Regulatory Class: II (two)
Product Code: 74 DSK
Dated: September 30, 1999
Received: October 8, 1999

Dear Dr. Morris:

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"(21 CFR 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,

for 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

510(k) NUMBER (IF KNOWN): K983250

DEVICE NAME: Invasive Blood Pressure Function, Model 9500 Multigas Monitor

INDICATIONS FOR USE:

Invasive blood pressure function is an option for the Model 9500 Multigas monitor. This function would be used when a clinician determined the need for continuous monitoring of arterial or venous blood pressure for adult patients undergoing MRI examination.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983250

(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-