

K972535

JAN 13 1998

APPENDIX B

Revised 510(k) Summary

**510(k) Summary for
Maglife C**

1. Date this summary was prepared: October 13, 1997

2. Submitter's Name and Address

O.D.A.M.
19, avenue de la gare
67162 Wissembourg cedex, France

3. Contact Person

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4. Device Name

Trade/Proprietary Name: Maglife C

Common Name: MR Safe Patient Monitor

Classification Names: patient physiological monitor

5. Predicate Devices

The legally marketed devices to which equivalence is being claimed are:

- MAGLIFE, marketed by O.D.A.M. (K950264)

- MRI-Compatible Model 9500 manufactured by Magnetic Resonance Corp. (K954120)
- Omni Trak 3100 MRI manufactured by In Vivo Research (K864889)

6. Device Description

MAGLIFE C is a multi-parameter patient monitor which has been designed for use in the immediate vicinity of a Magnetic Resonance Imagers for the surveillance of patients undergoing MRI examinations. The parameters that can be monitored are electrocardiogram (ECG), pulse oximetry (SpO_2), pulse rate, partial carbon dioxide pressure at the end of expiration ($EtCO_2$), nitrous oxide concentration ($\%N_2O$), partial pressure of inspired carbon dioxide (min inspired CO_2), respiratory rate (RR), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), concentration of gas inspired and expired (isoflurane, halothane, enflurane, desflurane, sevoflurane), and fraction of inspired oxygen (FiO_2).

The monitor consists of a line-powered console (with optional back-up battery) which is placed outside the magnet bore, and appropriate electrodes, transducers, cables and tubes to allow the patient to be monitored during the examination. The console enclosure is a Faraday cage for the protection of sensitive electronic circuits.

7. Intended Use

MAGLIFE C is intended for monitoring electrocardiogram (ECG), pulse oximetry (SpO_2), pulse rate, partial carbon dioxide pressure at the end of expiration ($EtCO_2$), nitrous oxide concentration ($\%N_2O$), partial pressure of inspired carbon dioxide (min inspired CO_2), respiratory rate (RR), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), concentration of gas inspired and expired (isoflurane, halothane, enflurane, desflurane, sevoflurane), and fraction of inspired oxygen (FiO_2) in the immediate vicinity of Magnetic Resonance Imagers for the surveillance of patients undergoing MRI examinations.

8. Comparison of Technological Characteristics

All four MRI compatible patient monitors employ established measurement methods combined with non-metallic sensors and fiber optic signal transmission to minimize the risk of burns and special shielding and filtering to minimize interference to and from the MRI unit.

9. Nonclinical Tests Used in Determination of Substantial Equivalence

The design of the Maglife C has been thoroughly validated at the unit and system level. Non-clinical tests were conducted to demonstrate compliance with the following standards:

- Cardiac Monitors, Heart Rate Meters, and Alarms.
ANSI/AAMI EC13 - 1992
- American National Standard for Pregelled ECG Disposable Electrodes.
ANSI/AAMI EC12 - 1991
- Electronic or Automated Sphygmomanometers.
ANSI/AAMI SP10
- Nonautomated Sphygmomanometers.
ANSI/AAMI SP9
- Blood Pressure Transducers.
ANSI/AAMI BP22 - 1994
- American National Standard for Interchangeability for Resistive Bridge Type Blood Pressure Transducers.
ANSI/AAMI BP23 - 1986
- Safe Current Limits for Electromedical Apparatus
ANSI/AAMI ES21 1993
- IEC 601-1

Maglife C has been evaluated with respect to the recommendations for electrical testing included in the November 1993 Reviewer Guidance for Premarket Notification Submissions (Anesthesiology and Respiratory Devices Branch).

Tests were conducted in an MRI unit to determine the maximum field strength that Maglife C can withstand without degradation of performance and to verify that the amount of ferrous material in the Maglife C is sufficiently small so that movement of the unit due to magnetic attraction is not possible.

Tests were conducted to assess the effect of the Maglife C on the Homogeneity of the magnetic field inside the magnet bore. These tests, using a 1.5 Tesla MR unit, showed that the Maglife could be placed as close as 60 cm from the front of the opening from the magnet without causing any visible difference in the images.

10. Conclusions From Nonclinical Testing

The testing of the Maglife C demonstrates that the performance is substantially equivalent to predicate devices cited above.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

O.D.A.M.
c/o Mr. James R. Veale
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 92760

JAN 13 1998

Re: K972535
Maglife C
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: October 13, 1997
Received: October 15, 1997

Dear Mr. Veale:

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 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/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

510(k) Number (if known): K972535

Device Name: Maglife C

Indications For Use:

The Maglife C is a multi-parameter patient monitor which is indicated for monitoring electrocardiogram (ECG), pulse oximetry (SpO₂), pulse rate, partial carbon dioxide pressure at the end of expiration (EtCO₂), nitrous oxide concentration (%N₂O), partial pressure of inspired carbon dioxide (min inspired CO₂), respiratory rate (RR), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), concentration of gas inspired and expired (isoflurane, halothane, enflurane, desflurane, sevoflurane), and fraction of inspired oxygen (FiO₂) in the immediate vicinity of a Magnetic Resonance Imagers for the surveillance of patients undergoing MRI examinations.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972535

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use