K023195
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JUN - 3 2003

510(k) Summary for MAGLIFE C/MAGLIFE C Plus

1. Date this summary was prepared: February 5, 2003

2. Submitter's Name and Address

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3. Contact person

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4. Device Name

Trade/Proprietary Name:	Maglife C/Maglife C Plus
Common Name:	MR Safe Patient Monitor
Clasification 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)
- Model 3100 LUXTRON CK

6. Device Description

The Maglife C is a multi-parameter patient monitor which is indicated 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) and temperature tracking.

The monitor consists of line-powered console (with optional back-up battery) which is placed outside the magnet boren, 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) and temperature tracking 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 Substancial Equivalence

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

- IEC 601-1
- IEC 601-1-2

Test 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2003

Schiller Medical SA
c/o Mr. Court Goehry
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BP 90050
67162 Wissembourg Cedex
France

Re: K023195
Trade Name: Maglife C/Maglife C Plus
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II (two)
Product Code: MWI
Dated: May 2, 2003
Received: May 8, 2003

Dear Mr. Goehry:

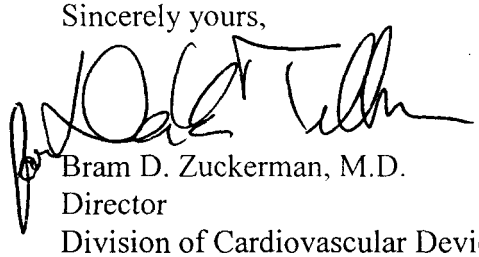
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023195

510(k) Number (if known): _____

Device Name: Maglife C Plus

Indications For Use:

The Maglife C is a multi-parameter patient monitor which is indicated 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) and temperature tracking 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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K023195

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)