K062974
p1/2

510(k) Number: _____

Date: _____

AUG 13 2007

510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Strasse 6
82291 Mammendorf
Germany

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors, Inc.
13605 West 7th Ave.
Golden, CO 80401 USA

Date Prepared

September 26, 2006

Trade Name of Device

Tesla NIBP

Common Name of Device

Patient Physiological Monitor (without arrhythmia detection)

Classification Name

Patient Physiological Monitor (without arrhythmia detection)

510(k) Classification

Class II under regulation 21 CFR 870.1130

Device Description and Intended Use

The ***Tesla***$^{NIBP®}$ Blood Pressure Monitor is an automatic non-invasive blood pressure (NIBP) measurement system that is intended for use in an MR-environment at a maximum magnetic field strength of 20mT. The completed system meets the requirements of AAMI standard SP10:2002+A1:2003. The ***Tesla***$^{NIBP®}$ design makes it possible to position the system within an RF-shielded MRI-room.

K062974
p 2/2

510(k) Number: _____

Date: _____

The device is intended to be used in the MRI-environment where patient care is provided by Healthcare Professionals, i.e. physicians, and nurses, trained on the use of the device, who will determine when use of the device is indicated based upon their professional assessment of the patient's medical condition.

The ***Tesla***$^{NIBP®}$ measures and displays:

1. Systolic Pressure
2. Diastolic Pressure
3. Heart Rate (BPM)
4. Mean Arterial Pressure (MAP)

MIPM will distribute pressure cuffs for use with the ***Tesla***$^{NIBP®}$ that are manufactured by other medical device manufacturing companies, and which are already cleared by FDA for sale in the USA.

Predicate Devices

Omega™ 1400 MRI monitoring system, as manufactured by Invivo Diagnostics Imaging.

Omron HEM 711AC, as manufactured by Omron Healthcare, Inc., Vernon Hills, IL.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

Mammendorfer Institut für Physik und Medizin GmbH believes that the Tesla NIBP is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2007

Medical Device Regulatory Advisors
c/o Mr. Robert N. Clark
President and Senior Consultant
13605 West 7th Ave.
Golden, Colorado 80401

Re: K062974
Tesla NIBP
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: July 19, 2007
Received: July 23, 2007

Dear Mr. Clark:

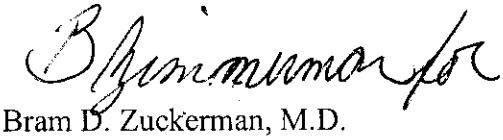
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K062774

Indications for Use

510(k) Number (if known): _____

Device Name: ___*Tesla*$^{NIBP®}$_____

Indications for Use:

The ***Tesla***$^{NIBP®}$ monitor is an automatic oscillometric measuring system designed to take non-invasive blood pressure measurements. It measures systolic pressure, diastolic pressure, mean arterial pressure and heart rate.

The ***Tesla***$^{NIBP®}$ monitor is intended to be used on neonate, pediatric and adult populations during MR-examinations at a maximum magnetic field strength of 20mT.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062774