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) Submitter

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82291 Mammendorf, Germany

510(k) Correspondent

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Date Prepared

June 25, 2007

Trade Name of Device

Tesla Guard®

Common Name of Device

MRI Compatible Patient Monitor

Classification

Name: Monitor, Physiological, Patient (without arrhythmia detector or alarms)
Product Code: MWI
Regulation Number: 21CFR§870.2300
Device Class: II

Device Description and Intended Use

The TeslaGuard design allows monitoring of intensive care patients while in an MRI-scanner. During use, the unit must be positioned in a way that the maximum field strength is not higher than 20 mT, and the distance to the magnet core is at least 1.5m.

This 510(k) has been filed to establish substantial equivalence for an optional multi-gas module. With the multi-gas module installed, sampled breathing gases from adults and pediatrics can be displayed. The multi-gas module continuously measures the content of CO2, N2O, O2 and one

of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture, and communicates real time and derived gas information to the TeslaGuard Patient Monitor.

The other intended uses of the TeslaGuard remain unchanged.

Predicate Devices

MIPM TeslaGuard® as cleared under 510(k) # K052119
Draeger Infinity Gamma XL as cleared under 510(k) # K053484

Non Clinical Testing

Laboratory bench testing was conducted to validate performance specifications of the multi-gas module. Simulated use testing was conducted to establish safety and effectiveness of the TeslaGuard multi-gas module under maximum intended MRI conditions.

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.

Substantial Equivalence

Mammendorfer Institut für Physik und Medizin GmbH (MIPM) believes that the TeslaGuard multi-gas module 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

NOV 0 9 2007

Mammendorfer Institut für Physik und Medizin GmbH
c/o Mr. Robert N. Clark
President and Senior Consultant
Medical Device Regulatory Advisors, Inc.
13605 West 7th Ave.
Golden, CO 80401

Re: K071802
Trade/Device Name: Tesla Guard Model EFT G04
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 7, 2007
Received: October 10, 2007

Dear Mr. Clark:

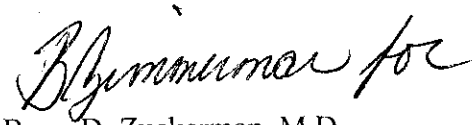
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Indications for Use

510(k) Number (if known): K071802

Device Name: ***Tesla***$^{Guard\ ®}$

Indications for Use:

The ***Tesla***$^{Guard\ ®}$ Patient Monitor is capable of monitoring:

- SpO2 (Arterial Oxygen Saturation)
- ECG (3-Lead)
- IBP (Invasive Blood Pressure)
- NIBP (Non-invasive Blood Pressure)
- CO2 and Anesthetic Agents (with optional multi-gas module)

This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings.

With the optional multi-gas module installed, sampled breathing gases from adults and pediatrics can be displayed. The multi-gas module continuously measures the content of CO2, N2O, O2 and one of the anesthetic agents, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane in any mixture, and communicates real time and derived gas information to the ***Tesla***$^{Guard\ ®}$ Patient Monitor.

The device is intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, 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 device is intended for use in the Adult, Pediatric and Neonatal populations.

MRI Compatibility Statement

The ***Tesla***$^{Guard\ ®}$ Patient Monitor is designed for use in an MRI-environment 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071802