schwarzer
Medical Equipment for Diagnosis

K023015

SEP 25 2002

510(k) Summary

Date 30.04.2002

Manufacturer
Schwarzer GmbH
Medical Equipment for Diagnosis
Baermannstr 38
D-81245 Munich
Germany

Contact Person Juergen Neubert, President
Telephone +49 89-83942-1
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Device Trade Name

cardis

Classification

Device Classification Name Computer, diagnostic, programmable
Classification / Panel Class II / Cardiovascular
Product Code DQK
Regulation Number 870.1425

Predicate Device

Legally marketed device to which equivalence is being claimed: **CATHCOR Desktop**
510(k) Number K0021137

Applied Guidances

- Diagnostic ECG Guidance (Including Non-Alarming ST Segment Measurement);
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices;
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Used in Medical Devices.

Indications for Use

The Schwarzer cardis heart catheter measuring systems with hemodynamical evaluation software are indicated for the registration, display, real-time recording, printout and storage of biophysiological data. Hemodynamic signals as intracardiac pressure and ECG signals are recorded and displayed and a number of hemodynamic calculations are performed based on the measured values of the input signals.

The Schwarzer cardis systems are intended for use in catheterization labs.

The Schwarzer cardis systems are indicated for use with patients of all ages under direct supervision of a physician or other trained health care professionals.

Comparison to Predicate Device

cardis systems are equivalent to the predicate device. Physical and technical characteristics including design, safety and efficacy characteristics and intended use of the cardis systems and the predicate device are either identical or comparable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2002

Schwarzer GmbH
c/o Mr. Mark Job
TPR Program Manager
TÜV Product Service
1775 Old Highway 8
New Brighton, MN 55112-1891

Re: K023015
Trade Name: Cardis
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: August 19, 2002
Received: September 10, 2002

Dear Mr. Job:

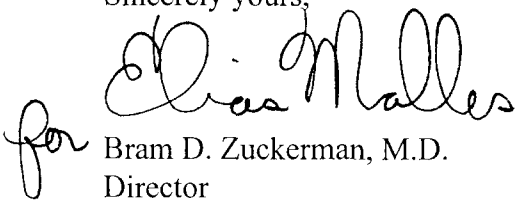
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

Enclosure

Indications for Use Statement

510(k) Number: K023015

Device Name cardis

Indications for Use:

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number Elias Mallis

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