510（K）Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter:

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OCT 22 2009

Contact person:

Jiang yucai
Edan Instruments, Inc.

Date: 2009-6-29

Proprietary Name: PC ECG

Classification Name: 21 CFR 870.2340 Electrocardiograph

Product code: DPS

Predicate Devices: Cardiosoft/case cardiac testing system K031561
Manufacturer: GE medical systems information technologies

Device Description:

PC ECG including model SE-1010 has the similar functions of an ordinary electrocardiograph. ECG data can be sampled, displayed and stored in PC machine, and they can be printed with several kinds of printing types, including PDF format, word format and JPG format. ECG wave can be frozen and reviewed. Auto measurement and diagnosing is available, and Diagnose Template can be edited.

PC ECG has the features as follows:

- 3/6/12-channel ECG wave display and printing simultaneously
- ECG wave frozen and review
- Measurement point adjustment and re-analyzing, manual measurement with high precision electronic ruler

- data management and processing function
- Report printing with PDF format, word format or JPG format
- Multi-language supporting
- Supporting auto measurement and diagnosing
- Automatic baseline adjustment for optimal printing

Intended Use:

SE-1010 PC ECG is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-1010 PC ECG is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Test Summary:

The following quality assurance measures were applied to the development of the Fetal & Maternal Monitor

- Software testing
- Risk analysis
- Safety testing
- Environment test

Conclusion:

Verification and validation testing was done on PC ECG.. This premarket notification submission demonstrates that PC ECG is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 22 2009

Edan Instruments, Inc.
c/o Mr. William Stern
Multigon Industries, Inc.
1 Odell Plaza
Yonkers, NY 10701

Re: K092010
PC ECG Model SE-1010
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: Undated
Received: September 17, 2009

Dear Mr. Stern:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indication for Use

510(k) Number (if known): K092010

Device Name: PC ECG

SE-1010 PC ECG is intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. SE-1010 PC ECG is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 PC ECG can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Prescription Use ___X___ Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K092010