510（K）Summary of Safety and Effectiveness

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

JUN - 3 2009

Submitter:

Edan Instruments, Inc
3/F - B, Nanshan Medical
Equipments Park, Nanhai Rd 1019#,
shekou, Nanshan Shenzhen,
518067 P.R. China
Tel: +86755 26882220
Fax:+86 755 26882223

Contact person:

Jiang yucai
Edan Instruments, Inc.

Proprietary Name: SE-601 Series Electrocardiograph

Classification information: 21 CFR 870.2340, Electrocardiograph
Class II

Product code: DPS

Review Panel: Cardiovascular

Predicate Devices: ECG-1250A SERIES CARDIOFAX S AND ECG-1350A SERIES CARDIOFAX M K072217
Manufacturer: NIHON KOHDEN AMERICA, INC

Device Description: SE-601 series Smart ECG includes three models SE-601A, SE-601B and SE-601C.
Device features include as follows:

- Portable, lightweight design
- Easy data input and operation
- Alphanumeric keyboard and one-touch operation
- Built-in rechargeable battery, AC/DC power supply
- Automatic analysis and diagnostic software (SEMIP) for adults
- Heart rate variability (HRV) analysis
- Internal thermal printer and external printer

- Support external archiving: USB flash disk, card reader
- Data transmission to PC via Ethernet or serial port

Intended Use:

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

Test Summary:

The following quality assurance measures were applied to the development of the SE-601 Series Electrocardiograph:

- Software testing
- Risk analysis
- Safety testing
- Performance test

Conclusion:

Verification and validation testing was done on SE-601 Series Electrocardiograph. This premarket notification submission demonstrates that the subject device SE-601 Series Electrocardiograph is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN - 3 2009

Re: K090367
SE-601 Series Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Codes: DPS
Dated: April 9, 2009
Received: April 29, 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); 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

Indication for Use

510(k) Number: K090367

Device Name: SE-601 Series Electrocardiograph

The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface with ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is only intended to be used on adult patients and is offered to clinicians 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)

for B Zuckerman

(Division Sign-Off) 6/2/09

Division of Cardiovascular Devices

510(k) Number K090367