Re: K091513

Attachment 3

JUL 24 2009

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: Edan Instruments, Inc
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Contact person: Jiang Yucai

Official correspondent: William Stern
Multigon Industries,Inc.
1 Odell Plaza
Yonkers, N.Y. 10701
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Date of Preparation: 4/21/2009

Proprietary Name: Electrocardiograph

Common Name: Electrocardiograph

Classification Name: 21 CFR 870.2340 Electrocardiograph DPS
Class II

Predicate Devices: MAC 5000 ECG Analysis System K014108

Device Description: The Smart ECG (SE) Series Electrocardiograph is designed to acquire, analyze, display, and record ECG signals from patient body surface by ECG electrodes. After been amplified, filtered and analyzed, The ECG signals waveforms and analysis results are displayed in the LCD and recorded in the paper through thermal printer or USB printer. ECG data, result and information of patient may be stored in the memory file. The file can be transmitted to PC through UART or Ethernet. Also the device can configure with the auto analysis software as optional which help to carry out auto measurement and auto interpretation.

These devices consist of two basic components: the signal acquisition module and central processing unit. Models provide rechargeable battery.

The SE Series Electrocardiograph can be divided into two type

devices, SE-3, SE-300 series and SE-12, SE-1200 series,.

SE-3, SE-300 series are three channels Electrocardiograph, Including SE-300A, SE-300B, SE-3 (configuration with A and configuration with B) , it can print out three channel electrocardiograph wave simultaneously by an 80mm wide thermal line printer. The difference between SE-3 and SE-300 is the device shell.

SE-12, SE-1200 series are twelve or six channel Electrocardiograph, including SE-12, SE-12Express, SE-6, SE-1200, SE-1200Express, SE-600, it can print out twelve or six channel electrocardiograph wave simultaneously by a 216mm wide thermal line printer. the difference between SE-12 and SE-1200 is the device shell.
The SE series Electrocardiograph is not intended to use in the emergency monitoring room.

Intended Use The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface 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 ECG with measurements and interpretive statements is offered to clinician on an advisory basis only

Contraindications: None known at this time

Technology: The technological characteristics of the SE-12 device have been updated to reflect use of current technology and to incorporate user-requested features. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety or effectiveness.

Test Summary: The following quality assurance measures were applied to the development of the SE Electrocardiograph

- Software testing
- Hardware testing
- Safety testing
- Electric Magnetic Compatibility testing

Conclusion: Verification and validation testing was done on the SE Electrocardiograph. This premarket notification submission demonstrates that the SE Electrocardiograph is substantially

equivalent to the cleared MAC 5000 because this device has the same basic intended use and the differences in technological characteristics do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2009

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

Re: K091513
SE series Electrograph (models: SE-3, SE-300A, SE-300B, SE-6, SE-600, SE-12, SE-12Express, SE-1200, SE-1200Express)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: July 07, 2009
Received: July 09, 2009

Dear Mr. Stern:

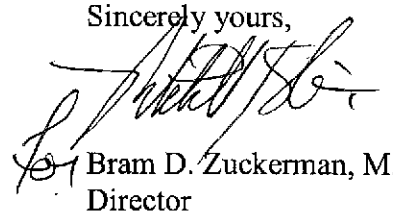
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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

K091513

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Indication for Use

510(k) Number (if known):K091513

Device Name: SE series Electrocardiograph (models: SE-3, SE-300A, SE-300B, SE-6, SE-600, SE-12, SE-12Express, SE-1200, SE-1200Express)

The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface 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 ECG with measurements and interpretive statements is offered to clinician on an advisory basis only

Prescription Use X And/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) 7/24/09
Division of Cardiovascular Devices
510(k) Number K091513