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DyAnsys

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of Safe Medical Devices Act (SMDA) 1990 and 21 CFR 807.92.

510(k) Number: _____

Applicant Information:

JAN 16 2008

Date Prepared: 17th Nov 2007

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Contact Person: Srini Nageshwar
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Device Information:

Classification: Class II
Trade Name: Portable ECScope 12*i*
Common Name: ECG Monitor
Classification Name: Electrocardiograph

Predicate Devices:

a. K Number: K072353,
Model Name: Portable ECScope
Manufacturer – DyAnsys, Inc

b. K Number: K954980,
Model Name: M 1770A Pagewriter 200
Manufacturer - HEWLETT-PACKARD CO

c. K Number: K032200
Model Name: ELANO Digital 12 Channel Electrocardiograph
Manufacturer – REMCO ITALIA S.P.A

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Device Description:

Portable ECScope 12*i* is designed to acquire, display and record ECG signals from surface electrodes. The device consists of two basic components: the processing unit and the patient acquisition module.

Portable ECScope 12*i* is a multi channel electrocardiograph for the simultaneous acquisition of the 12 ECG leads i.e L1, L2, L3, aVR, aVL, Avf, V1, V2, V3, V4,V5 & V6, featuring 3-lead Display Unit, alphanumeric keyboard and an option to print the ECG data using the Print Tool on A4 Sheet Paper or Direct Printing through connected printer.

Portable ECScope 12*i* can record and store in its Database up to 34 ECG tests. Each ECG test can include patient data, doctor's information and ECG measurements. Stored ECG tests can be reviewed and printed on the external printer using a PC.

Intended Use:

Portable ECScope 12*i* hand held, battery operated 12 channel electrocardiograph is intended to be used for the evaluation of the cardiovascular system. Portable ECScope 12*i* will acquire, record 12 ECG leads simultaneously, and display 3 leads at a time in its display unit.

Portable ECScope 12*i* is intended to be used by a licensed health care practitioner or under the direct supervision of a licensed health care practitioner in a hospital or health care environment. These measurements are not intended for a specific clinical diagnosis. The clinical significance of the ECG tracings must be determined by the physician in conjunction with clinician's knowledge of patient, the results of physical examination and other clinical findings.

Comparison to Predicate Device(s):

The Portable ECScope 12*i* is substantially equivalent to the following predicate devices:

a. K Number: K072353,
Model Name: Portable ECScope
Manufacturer – DyAnsys, Inc

b. K Number: K954980,
Model Name: M 1770A Pagewriter 200
Manufacturer - HEWLETT-PACKARD CO

c. K Number: K032200
Model Name: ELANO Digital 12 Channel Electrocardiograph
Manufacturer – REMCO ITALIA S.P.A

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1. Portable ECScope 12*i* handheld battery operated Multi channel electrocardiograph is intended to be used for the evaluation of the cardiovascular system. Portable ECScope 12*i* will acquire, display and record Multi channel ECG signal. Portable ECScope 12*i* can store in its database up to 34 ECG signal records. The device features a 10 lead ECG.

2. The Portable ECScope 12*i* has the same intended use as the legally marketed predicate devices. The intended use of the Portable ECScope 12*i* is the same as the predicates.

3. The Portable ECScope 12*i* was subjected to safety and performance tests against regulatory standards. Final testing for the product included various performance tests as per ANSI/AAMI EC11: 1991 Guidance Document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 2008

DyAnsys, Inc.
c/o Mr. Srini Nageshwar
CEO
Emery & Howard
577, Airport Boulevard, Suite 610
Burlingame, CA 95032

Re: K080036
Portable ECScope 12*i*
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: January 02, 2008
Received: January 07, 2008

Dear Mr. Nageshwar:

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

K080036

Indications for Use

510(k) Number (if known): K080036

Device Name: Portable ECScope 12*i*

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080036

(Posted November 13, 2003)