AUG 3 1 2007

[redacted]

3 510(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: K071168

Applicant Information:

Date Prepared: August 8, 2007

Name: DyAnsys, Inc.,
Address: c/o Emery & Howard,
577, Airport Boulevard, Suite 610,
Burlingame, CA 95032
Phone: 650.579.7100
Fax: 650.579.7313

Contact Person: Michael A. Daniel
Phone Number: Office: 925-254-5228 / Cell 415-407-0223
Facsimile Number: (925) 254-5187
madaniel@clinregconsult.com

Device Information:

Classification: DPS/class II/870.2340
Trade Name: The Portable ANSiscope™
Common Name: ECG Monitor
Classification Name: Electrocardiograph

Predicate Devices:

The Qmed monitor one nDx	K972991
The D.E.Hokanson, Inc. ANS2000	K973426
The Anscore System	K991831
The MAC 500 ECG Analysis System	K991735

Device Description:
The Portable ANSiscope™ is a device used for measuring heart rate variability (HRV). The device is designed to process raw ECG signals acquired from the patient in order to produce Heart Rate and other ancillary indices. The Portable ANSiscope™ includes an ECG Acquisition System that can digitize raw ECG signals, perform proprietary calculations from the HRV and then display the results utilizing a display unit.

[redacted]

Intended Use:

The DyAnsys, Inc. ANSiscope™ ECG Monitoring System and accessories, is intended to acquire, analyze, display and record electrocardiographic information and to measure-heart rate variability. These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

Comparison to Predicate Device(s):

The Portable ANSiscope™ is substantially equivalent to the following predicate devices:

The Qmed monitor one nDx	K972991
The D.E.Hokanson, Inc. ANS2000	K973426
The Anscore System	K991831
The MAC 500 ECG Analysis System	K991735

1. The Portable ANSiscope™ is a portable system with a computer-based user interface and data acquisition system for testing, data collection and analysis. The device features a 5 lead ECG.
2. The Portable ANSiscope™ has the same intended use as the legally marketed predicate devices. The Portable ANSiscope™ is intended for use in Heart Rate Variability (HRV) measurements. . Though the measurement technology and the technological characteristics are not the same as those of the legally marketed devices, the new characteristics do not affect the safety and effectiveness.
3. The Portable ANSiscope™ was subjected to safety and performance tests against applicable recognized standards. Final testing for the product included various performance tests to confirm compliance with functional requirements and performance specifications.
4. The Portable ANSiscope utilizes proprietary software within the device based on scale covariance physics to calculate the interactivity of certain "tool parameters" from the supine recordings. The ANSiscope extracts beat-by-beat information from the RR time-intervals of the ECG. Indices are calculated giving activity-degrees of subsystems locally. The ANSiscope considers the interactivity as the lack of coupling of these indices and then defines its measurement as a percentage of interactivity over the time period considered (512 indices are required). The lack of coupling is measured by a metric between indices in the optimal phase. The obtained interactivity measurements form aggregates of values whose boundaries define groups that can aid diagnosis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2007

DyAnsys, Inc.
c/o Mr. Michael A. Daniel
Emery & Howard
577 Airport Boulevard, Suite 610
Burlingame, CA 95032

Re: K071168
Trade/Device Name: Portable ANSiscope ECG Monitoring System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: August 29, 2007
Received: August 30, 2007

Dear Mr. Daniel:

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.

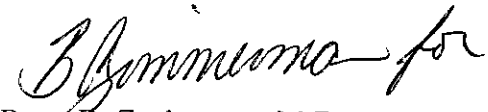
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21CFR 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

5 INDICATIONS FOR USE FORM

510(k) Number (if known): TBD K071168

Device Name: The Portable ANSiscope™

Indications for Use:

The DyAnsys, Inc. ANSiscope™ ECG Monitoring System and accessories, is intended to acquire, analyze, display and record electrocardiographic information and to measure-heart rate variability. These and other measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV and other parameters must be determined by the physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071168