NORAV medical

Summary of Safety and Effectiveness

510(k) Summary

21 CFR 807.92(c)

NOV 10 2011

Submitter

21 CFR 807.92(a)(1)

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Manufacturer

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Contact: David Seal – QA Manager david@norav.com

Device Name:

PCECG-1200 System With Modular ECG Analysis System (MEANS) **21 CFR 807.92(a)(2)**

Trade Name: ***PCECG-1200 System With MEANS***

The classification name 1	monitor, physiological, patient (without arrhythmia detection or alarms)
Regulation Number 1	870.2300
Classification code 1	MWI
The classification name 2	transmitters and receivers, electrocardiograph, telephone
Regulation Number 2	870.2920
Classification code 2	DXH

Substantial Equivalence 21 CFR 807.92(a)(3)

1. Norav's *PC ECG 1200W* System k080141 for complete physical and functional identity
2. Welch Allyn's CardioPerfect Workstation (CPWS) V 1.6.2 Software k082478 (developed by P. Rijnbeek) on the grounds of close similarity

Device Definition 21 CFR 807.92(a)(4)

The *PCECG-1200 System With Modular ECG Analysis System (MEANS) is* designed to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value. The System comprises:

- Data Acquisition Unit
- RF transceiver
- USB communications cable
- Software application
- Software access security lock (dongle), optional

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The system acquires ECG data and displays it on the color monitor, calculates and controls some parameters of ECG display such as sweep speed, filters line interference and muscle noises introduced during monitoring, makes necessary outputs, handles the user interface, and controls the flow of operations.

Acquired data is stored, and subsequently transferred to the PC for display. Up to 12 channels of real time ECG display are possible. The available commands, calculation of results and status messages are also displayed. All commands are initiated via keyboard.

Intended Use 21 CFR 807.92(a)(5)

ECG intended use:

ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in patients:

1) suspected of cardiac abnormalities, or

2) in populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics are desired.

3) QT Analysis is useful in the assessment of long QT syndrome (LQTS). In some instances, LQTS can be corrected by pharmacologic therapy. QT analysis is also used to measure QT dispersion, the difference between maximal and minimal QT values. QT dispersion is a measure of the inhomogeneity of ventricular repolarization.

4) The PCECG-1200 System With MEANS has been tested to measure Heart Rate Variability within 1 millisecond tolerance. The clinical significance of HRV measures should be determined by a physician.

5) The PCECG-1200 System With MEANS has been tested to measure Late Potential within 1 millisecond tolerance in the time domain, and 1 microvolt tolerance in voltage. The clinical significance of Heart Rate Variability measures should be determined by a physician.

Stress testing intended use:

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of a reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present. Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thereby coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG during patient exercise. Patients are exercised by bicycle, treadmill, or other means while continuously monitoring the ECG. Exercise loads are determined by predefined protocols. The ECG signals are recorded for the resting, exercise and recovery portions of the exercise protocol. The changes in ECG waveforms are compared to the resting ECG records. Although not necessary, most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database has been used as a tool for performance testing. The significance of the ST segment changes must be determined by a physician.

Technological characteristics 21 CFR 807.92(a)(6)

The system acquires ECG data and displays it on the color monitor, calculates and controls some parameters of ECG display such as sweep speed, filters line interference and muscle noises introduced during monitoring, makes necessary outputs, handles the user interface, and controls the flow of operations.

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Acquired data is stored, and subsequently transferred to the PC for display. Up to 12 channels of real time ECG display are possible. The available commands, calculation of results and status messages are also displayed. All commands are initiated via keyboard.

ECG is analyzed by the Modular ECG Analysis System (MEANS), which is a cleared O.E.M. SW Application obtained by Norav from the producer: the Department of Medical Informatics Erasmus University Medical Center Rotterdam, the Netherlands.

Recognized Consensus Standards

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

IEC 60601-2-25 Amendment 1 (1999), Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs

IEC 60601-2-27 (1994) Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment

ISO 14971:2007, Medical devices - Application of risk management to medical devices

Summary 21 CFR 807.92(b)(3)

PCECG-1200 System With MEANS System constitutes a safe and reliable medical device. Similarly to the predicate devices, the System operation presents no adverse health effect or safety risks to patients when used as intended.

Name: David Seal Position: QA Manager

Signature: D. Seal Date: 18 September 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 10 2011

Norav Medical Ltd.
c/o Mr. Benny Arazy
Arazy Group – Medical Device Consultants
Industrial Park 13, M.P. Misgav
Mitzpe Aviv
Israel 20197

Re: K110463
Trade/Device Name: PCECG-1200 System With MEANS
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: September 21, 2011
Received: October 11, 2011

Dear Mr. Arazy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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,

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

Enclosure

K110463 pg 1 of 1

Indications for Use

510(k) Number (if known):

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Prescription Use [X] _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K110463

(Posted November 13, 2003)