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Summary of Safety and Effectiveness

510(k) Summary

21 CFR 807.92(c)

Submitter 21 CFR 807.92(a)(1)

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Manufacturer

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Device Name:

NH-301 Ambulatory ECG Analysis Software 21 CFR 807.92(a)(2)

Trade Name: NH-301 Ambulatory ECG Analysis Software

The classification name 1	electrocardiograph, ambulatory, with analysis algorithm
Regulation Number 1	870.2800
Classification code 1	MLO
The classification name 2	transmitters and receivers, electrocardiograph, telephone

Substantial Equivalence 21 CFR 807.92(a)(3)

Norav's NH-300 Holter Analysis System k012712 for complete structural and functional identity of both software applications as well as their intended use and indications for use.

The only difference between the applications is that NH-300 is designed for monitoring 1 to 48 hours of Holter records, while NH-301 is capable of monitoring up to 168 hours.

Device Definition 21 CFR 807.92(a)(4)

The *NH-301 Ambulatory ECG Analysis Software* is designed to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value.

Indications for Use and Intended Use 21 CFR 807.92(a)(5)

The ***NH-301 Ambulatory ECG Analysis Software*** is intended for patients requiring ambulatory (Holter) monitoring from 1 to 168 hours. Such monitoring is most frequently used for the following indications:

1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
2. Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients.
3. Evaluation of patients for ST segment changes.
4. Evaluation of patient's response after resuming occupational or recreational activities, (e.g., after M.I. or cardiac surgery.)
5. Clinical and epidemiological research studies.

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6. Norav Holter Systems containing Heart Rate Variability (HRV) software have been tested to measure Heart Rate Variability within 4 ms tolerance. The clinical significance of Heart Rate Variability measures should be determined by a physician.
7. Evaluation of patients with pacemakers

Technological characteristics 21 CFR 807.92(a)(6)

The Software uploads long term ECG data from compatible ambulatory ECG recorders, analyzes via an algorithm and then displays it on the color monitor, in a manner that allows the analyses to be edited and reported. Several parameters are adjustable in the set-up of the analysis system.

The Software has an open architecture designed to operate on various IBM PC or compatible. It uses a high resolution printer. Instead of designing a computer inside a medical instrument, the instrument is delivered as a software and interface assembly to be used with an off the shelf computer system. This technique enhances the system cost effectiveness and reliability.

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.

Recognized Consensus Standards

AAMI / ANSI EC38:2007, **Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems** (Cardiovascular)

IEC 60601-1-4:2000, **Medical electrical equipment - Part 1: General requirements for safety - 4 - Collateral standard: Programmable electrical medical systems**

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

Summary 21 CFR 807.92(b)(3)

The *NH-301 Ambulatory ECG Analysis Software* constitutes a safe and reliable medical device. Similarly to the predicate device, its operation presents no adverse health effect or safety risks to patients when used as intended.

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: K111487
Trade/Device Name: NH-301 Ambulatory ECG Analysis Software
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MLO
Dated: September 18, 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

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Indications for Use

510(k) Number (if known):

Device Name:

Indications for Use:

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5. Clinical and epidemiological research studies.
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7. Evaluation of patients with pacemakers

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)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111487