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JUN 1 0 2004

K040753

01/29/2004

SAFETY & EFFECTIVENESS DATA SUMMARY

Classification Name : Electrocardiograph
Common/Usual Name: ECG Event Recorder
Proprietary Name: R-Test Evolution 3

Establishment Registration Number : 9612397

Classification : Class II **Reg. Number** : 8702800

Performance Standards : Devices are manufactured according EN 60-601-1, 93/42/EEC – European Medical Device Directive, EN 46002, ISO 9001 (2000) and ISO 13485 (1996).

Material Composition :
Ag/AgCl Electrodes

Testing conducted to assure safety and effectiveness include but is not limited to :

Testing conducted for conformity to these standards

EN 60601-1
EN 60601-1-1
EN 60601-1-1-2
En 60601-1-1-4
En 55011

Note : This testing will be completed, reviewed and approved prior to release and distribution of this product.

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SAFETY & EFFECTIVENESS DATA SUMMARY

Description of the modified device :

The R-Test Evolution 3 is a miniature ambulatory ECG Recorder, which is easy to connect to the patient. The most advanced version (automatic mode) is capable of memorizing the most significant pathological events (symptomatic or silent) as well as the patient's continuous heart rate, and is capable of up to eight days ambulatory recording.

The system consists of a unit weighing about 40 grams and includes a lightweight cable which can be worn by the patient unobtrusively and without any discomfort. The R-Test Evolution 3 is connected to the patient by the electrodes and the cable.

Cardiac events are memorized by the R-Test Evolution 3 and then transferred for interpretation :

- either by a decoder, the Decotest to an electrocardiograph (or an ECG monitor), or to a computer,
- or by a cable directly to a computer.

This transfer is generally done at the physician's surgery at the following visit. It can also be teletransferred by phone or by e-mail, by modem, either from the patient's home, or from the office of a physician working in connection with an interpretation center.
The R-Test Evolution 3 can also transmit real time ECG recordings by telephone; and after reading or transmission the R-Test Evolution 3 can continue recording any further pathological events which may occur on the same patient.

Using a computer enables you to :

- define the conditions and criteria of the recordings to be made by the R-Test Evolution 3,
- to select, organize and store the patient data and the results of a procedure, and to print them using specific report parameters.

Intended use :

The R-Test Evolution 3 is a miniature ambulatory ECG Event Recorder that is connected to the patient. This version is capable of memorizing the most significant pathological events (symptomatic or silent) as well as the patient's continuous heart rate trend, and is capable of up to eight day ambulatory recording.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2004

Novacor, S.A.
c/o Ms. Dominique Grenier
4 Passage Saint-Antoine
92508 Rueil-Malmaison Cedex
FRANCE

Re: K040753
Trade Name: R-test Evolution 3
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MLO
Dated: March 19, 2004
Received: March 24, 2004

Dear Ms. Grenier:

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **R-TEST EVOLUTION 3**

Indications For Use:
The R-Test Evolution 3 is a miniature ambulatory ECG Event Recorder that is connected to the patient. As the R-Test Evolution (previous model), this version is capable of memorizing the most significant pathological events (symptomatic or silent) as well as the patient's continuous heart rate trend, and is capable of up to eight day ambulatory recording. The registered data could be sent by a modem or by an e-mail application software.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040753

Prescription Use ____X____ AND/OR Over-The-Counter Use N. A
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)