AUG 4 2000

SAFETY & EFFECTIVENESS DATA SUMMARY

NOVACOR

K993788

Classification Name: Ambulatory ECG Recorder
Common/Usual Name: Event Recorder
Proprietary Name: R. Test Evolution

Establishment Registration Number:

Classification: Class II **Reg. # 74IIDSH**

Performance Standards: Devices are manufactured according EN-60-601-1, 93/42 EEC – European Medical Device Directive and EN 46002 / ISO 9002.

Substantial Equivalence: Event Recorders are currently being marketed and distributed by Instromedix who currently holds a 510(k) #K880620 for King of Hearts Recorder and Novacor's R.Test 60 & 160 ECG Recorders, K844391, Marketed by AMS Medical.

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 55011
EN 55082-1
IEC 801-2, 3 & 4

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

SAFETY & EFFECTIVENESS DATA SUMMARY

Description of the new device:

The R-Test Evolution 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 neck cable which can be worn by the patient unobtrusively and without any discomfort. The R. Test Evolution is connected to the patient by a system of electrodes and the neck cable.

Cardiac events are memorized by the R. Test evolution and then transferred by a decoder, the Decotest, to an electrocardiograph or a computer for interpretation:

- **either directly at the physician's surgery at the following visit,**
- **or by being transmitted telephonically by the patient himself.**

The R. Test Evolution can also transmit real time ECG recordings by telephone. After making a telephonic or direct transfer, the R. Test Evolution can continue recording any further pathological events which may occur.

Using a computer enables you to:

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

Intended Use:

The R-Test Evolution is a miniature ambulatory ECG Event Recorder that is connected to the patient. This version (automatic mode) 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

AUG 4 2000

Novacor S.A
C/O Ms. Lynette L. Howard
Submission Correspondent
International Medical Products
203 Main Street, PMB 166
Flemington, NJ 08822-1610

Re: K993788
R.Test Evolution Event Recorder
Regulatory Class: II (two)
Product Code: 74 MLO
Dated: June 20, 2000
Received: June 26, 2000

Dear Ms. Howard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosures

STATEMENT OF INDICATIONS FOR USE

The R-Test Evolution is a miniature ambulatory ECG Event Recorder that is connected to the patient. This version (automatic mode) 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.

for Mark N Milhorn

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
Neurological Devices
510(K) Number K993788