

KY 12310

NIHON KOHDEN AMERICA, INC.  
June 19, 1997

510(k) NOTIFICATION  
QP-932E Exercise Test Option

**SECTION 2 - 510(K) SUMMARY**

AUG 20 1997

**Name and Address of Applicant**  
Nihon Kohden America, Inc.  
2601 Campus Drive  
Irvine, California 92612-1601

**Contact Person and Telephone**  
Mr. Gary Reasoner  
Director of Product Operations  
(714) 250-3959 ext. 3387

The QP-932E Exercise Test Option is an optional accessory for the Nihon Kohden Cardiofax, Model ECG-9320A Electrocardiograph, per 510(k) #K961272, commercial distribution certification dated November 1, 1996. The device has been classified as Class II by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 "Electrocardiograph" as per part 74 DPS.

Common names for the ECG-9320A Cardiofax device with the QP-932E Exercise Test Option include Electrocardiograph and Cardiograph.

The predicate devices are the Nihon Kohden Cardiofax, Model ECG-8340A Electrocardiograph per 510(k) #K865032, commercial distribution certification dated March 10, 1987 and the Quinton Instrument Company Model Q710 Exercise and Resting ECG System per 510(k) #K945626, commercial distribution certification dated June 28, 1995.

The QP-932E Exercise Test Option with its parent device, the Nihon Kohden Cardiofax ECG-9320A Electrocardiograph, is intended for medical purposes used to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and to prepare a record of the electrical signals produced by the heart. The QP-932E will develop a report based upon acquired data and subsequent calculations. The ECG-9320A with QP-932E Exercise Test Option will be available for use by a physician within a hospital, laboratory, clinic or in a remote environment under the supervision of a physician.

To date, no performance standards or special controls are known or established for this device as required by Section 514 of the Food, Drug and Cosmetic Act and implemented by 21 CFR part 861.

The device is not intended to be sterile.

The Nihon Kohden Cardiofax ECG-9320A Electrocardiograph was subject to electromagnetic, environmental, safety and performance testing. These tests verified the operation of the device.

Software validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the QP-932E Exercise Test Option for the ECG-9320A Cardiofax Electrocardiograph is substantially equivalent to the Nihon Kohden Cardiofax, Model ECG-8340A Electrocardiograph and the Quinton Instrument Company Model Q710 Exercise and Resting ECG System.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

AUG 20 1997

Mr. Gary Reasoner  
Nihon Kohden America, Inc.  
2601 Campus Drive  
Irvine, California 92715

Re: K972310  
Nihon Kohden QP-932E Exercise Test Option for the ECG-9320A  
Cardiofax Electrocardiograph  
Regulatory Class: II (two)  
Product Code: 74 DPS  
Dated: June 19, 1997  
Received: June 20, 1997

Dear Mr. Reasoner:

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 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 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.

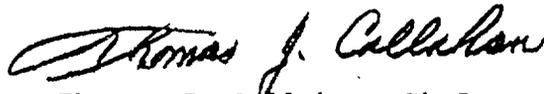
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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) 594-4648. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

G. Indications for Use Statement:

The QP-932E Exercise Test Option with its parent device, the Nihon Kohden Cardiofax ECG-9320A Electrocardiograph, is intended for medical purposes used to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and to prepare a record of the electrical signals produced by the heart. The QP-932E will develop a report based upon acquired data and subsequent calculations.

The ECG-9320A with QP-932E Exercise Test Option will be available for use by a physician within a hospital, laboratory, clinic or in a remote environment under the supervision of a physician.

FOR prescription user ✓

*[Signature]* 8/20/97  
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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K972310