K984504

APR 15

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601
(949) 250-3959

The ECG-9110K and ECG-9130K have been classified as Class III by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 "Electrocardiograph" as per 74 LOS.

Common names for the ECG-9110K and ECG-9130K include ECG and electrocardiograph.

Nihon Kohden's model ECG-9110K and ECG-9130K are intended for medical purposes to process the electrical signals transmitted through two or more electrocardiograph electrodes and to produce a visual display and/or prepare a record of the electrical signals produced by the heart.

The ECG-9110K and ECG-9130K devices comply with the IEC 601-1 standard including subclause 56.3(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for these devices. The devices are also in compliance with the following voluntary industrial standards: IEC 601-2-25 and CSA 601-1. Defibrillator Discharge Protection: Class I, Type CF.

The ECG-9110K and ECG-9130K are not intended to be sterile.

The devices were determined to be non-contacting. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The ECG-9110K and ECG-9130K were subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the ECG-9110K and ECG-9130K are substantially equivalent to the ECG-9320A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 1999

Mr. Gary Reasoner
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, CA 92612

Re: K984504
Nihon Kohden ECG-9110K and ECG-9130K Cardiofax Q
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: April 6, 1999
Received: April 7, 1999

Dear Mr. Reasoner:

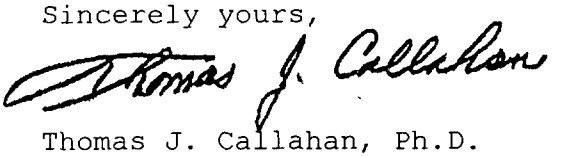
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 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 (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) 594-4648. 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/dsma/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

510(k) Number (if known): K984504

Device Name: ECG-9110K and ECG-9130K Cardiofax Q

Indications for Use:

The ECG-9110K and ECG-9130K Cardiofax Q electrocardiographs are intended for medical purposes to process the electrical signals transmitted through two or more electrocardiograph electrodes to produce a visual display and/or to prepare a record of the electrical signals produced by the heart.

For non-interpretive applications, the ECG-9110K and ECG-9130K are intended for use with a full range of patient populations as determined by a clinician. The devices also provide an interpretive ECG program intended for use with patients age 3 years to adult.

The interpretation program is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis. Assessments provided by the interpretation program are not intended as the sole basis for diagnosis. All assessments provided by the interpretation program are recommended for review by qualified physicians trained in electrocardiography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur C. Barkowski

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984504

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)