

K9M1355

NIHON KOHDEN AMERICA, INC.  
April 9, 1997

JUL 15 1997

510(k) NOTIFICATION  
TEC-7531A cardiolife

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

**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 TEC-7531A cardiolife is classified as Class III by the Division of Cardiovascular, Respiratory and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.5550 External Transcutaneous Cardiac Pacemaker (Non-invasive) as per Product Classification Code 74 DRO. Additional device classification is Class II by the Division of Cardiovascular, Respiratory and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.5300 DC-Defibrillator, Low-energy (including paddles) as per Product Classification Code 74 LDD, under 21 CFR Part 870.2300 Monitor, Cardiac Monitor (including Cardiometer and Rate Alarm) as per Product Classification Code 74 DRT and under 21 CFR Part 870.2910 Radiofrequency Physiological Signal Transmitter and Receiver as per Product Classification Code 74 DRG.

Common names for the TEC-7531A cardiolife are Low-energy DC-defibrillator, Cardiac Monitor, External Transcutaneous Cardiac Pacemaker, Radiofrequency Physiological Signal Receiver and Radiofrequency Physiological Signal Transmitter.

The predicate marketed devices are the Nihon Kohden cardiolife, TEC-7200A Portable Defibrillator per 510(k) #K863405, commercial distribution certification dated October 31, 1986, the Nihon Kohden cardiolife, TEC-8251A Portable Defibrillator per 510(k) #K913085, commercial distribution dated September 25, 1991, the Nihon Kohden Life Scope 14, BSM-8800A Bedside Monitor per 510(k) #K920154, commercial distribution dated December 18, 1992 and the Nihon Kohden Life Scope L, BSM-2101A Bedside Monitor per 510(k) #K914092, commercial distribution dated May 28, 1992.

Nihon Kohden's TEC-7531A cardiolife is intended for medical purposes. The device will deliver an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The electrical shock is delivered through paddles attached to the main unit. This device will supply a periodic electrical pulse intended to pace the heart when applied to the chest surface through electrodes. This device serves as a cardiac monitor, with the ability to measure heart rate and to sound an alarm when the heart rate falls outside preset upper and lower limits. This device will also condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g. a central monitoring station, and will recondition a physiological signal to its original format when received from another device, e.g. transmitter. The TEC-7531A cardiolife will be available for use by a physician, or under the supervision of a physician, within a medical facility and in remote environment.

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 TEC-7531A cardiolife was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing, displaying and recording of the devices. The results confirmed that the devices performed within specifications.

Therefore based on the preceding information, Nihon Kohden Corporation believes that the TEC-7531A cardiolife Portable Defibrillator is substantially equivalent to the predicate devices: the Nihon Kohden TEC-7200A cardiolife Portable Defibrillator, the Nihon Kohden TEC-8250A cardiolife Portable Defibrillator, the Nihon Kohden BSM-8800A Life Scope 14 Bedside Monitor and the Nihon Kohden BSM-2101A Life Scope L Bedside Monitor.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 15 1997

Mr. Gary Reasoner  
Nihon Kohden America, Inc.  
2601 Campus Drive  
Irvine, California 92612-1601

Re: K971355  
Nihon Kohden TEC-7531A Cardioline Portable  
Defibrillator and Accessories  
Regulatory Class: III (three)  
Product Code: 74 DRD  
Dated: April 9, 1997  
Received: April 11, 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.

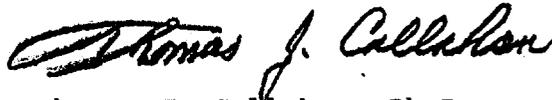
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

Page 2 - Mr. Gary Reasoner

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) 594-4646. 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

510(k) Number (if known): K9M1355

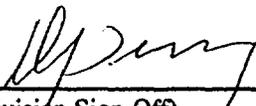
Device Name: TEC-7531A cardiolife Portable Defibrillator

Indications for Use:

Nihon Kohden's TEC-7531A cardiolife is intended for medical purposes. The device will deliver an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The electrical shock is delivered through paddles attached to the main unit. This device will supply a periodic electrical pulse intended to pace the heart when applied to the chest surface through electrodes. This device serves as a cardiac monitor, with the ability to measure heart rate and to sound an alarm when the heart rate falls outside preset upper and lower limits. This device will also condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g. a central monitoring station, and will recondition a physiological signal to its original format when received from another device, e.g. transmitter.

The TEC-7531A cardiolife will be available for use by a physician, or under the supervision of a physician, for adult and pediatric patients within a medical facility and in remote environment.

*Prescription Device*

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