

K971194

NIHON KOHDEN AMERICA, INC.
March 31, 1997

510(k) NOTIFICATION
TEC-6100A cardiolife

JUL - 9 1997

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-6100A cardiolife device is classified as 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 and under 21 CFR Part 870.2300 Monitor, Cardiac (including Cardiotachometer) as per Product Classification Code 74 DRT.

Common names for the TEC-6100A cardiolife device include Low-energy DC-defibrillator and Cardiac Monitor.

The predicate marketed devices are the Nihon Kohden cardiolife, TEC-7100A Portable Defibrillator per 510(k) #K863404, commercial distribution certification dated October 31, 1986 and the Nihon Kohden cardiolife, TEC-8250A Portable Defibrillator per 510(k) #K914971, commercial distribution dated December 3, 1991.

Nihon Kohden's cardiolife, model number TEC-6100A, 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. The device also serves as a cardiac monitor, with the ability to measure heart rate. The TEC-6100A cardiolife will be available for use by a physician or under the supervision of a physician, within a medical facility ~~and in a 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-6100A cardiolife device 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 device. The results confirmed that the device performed within specifications.

Therefore based on the preceding information, Nihon Kohden believes that the TEC-6100A cardiolife is substantially equivalent to the predicate devices: the Nihon Kohden TEC-7100A cardiolife and the Nihon Kohden TEC-8250A cardiolife.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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Re: K971194
Nihon Kohden TEC-6100A Cardioline Mini Defibrillator
Regulatory Class: II (two)
Product Code: 74 LDD
Dated: March 31, 1997
Received: April 1, 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 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.

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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

Indications for Use Statement

510(k) Number (if known): K971194

Device Name: TEC-6100A cardiolife Mini Defibrillator

Indications for Use:

Nihon Kohden's cardiolife, model number TEC-6100A, 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 device also serves as a cardiac monitor, with the ability to measure heart rate.

The TEC-6100A will be available for use by a physician or under the supervision of a physician, within a medical facility ~~and in a remote environment~~. This device is not intended for use in ambulances. The device is intended for use with adult and pediatric patients.

Richard N. Phillips
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971194

prescriptional use ✓