**510(K) SUMMARY** K102106 **DEC 17 2010**

- **Name and Address of Applicant**

Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, Ca 92610

Telephone: (949) 580-1555 Ext. 3325
Fax: (949) 580-1550
Attn: Steve Geerdes, Director of Regulatory Affairs

Date: July 20, 2010
Updated November 12, 2010

- **Name/Trade Name of the Device:** Prefense EDNS-9000 Series Central Nurse Station

- **The common or usual Name:** Monitor, physiological, patient (with arrhythmia detection or alarms) and Telemetry Monitoring Station.

- **The Classification:** The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Monitor, Physiological, Patient (with arrhythmia detection or alarms)" per MHX and 21 CFR 870.2910 "Radiofrequency physiological Signal Transmitter and Receiver per DRG.

- **The legally marketed equivalence:** The predicate devices are the Nihon Kohden Prefense EDNS-9000 Series Central Nurse Station and Accessories per 510(k) K073550 cleared on March 28, 2008 and the Nihon Kohden ORG-9700A Multiple Patient Receiver per 510(k) K071058 cleared on June 29, 2007

- **A description of the device:** The device is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The Prefense EDNS-9000 Series Central Nurse Station will display and record physiological data from up to forty telemetry receiver/transmitters and generates an alarm when a measured parameter falls outside a pre-set limit or when life threatening arrhythmia is detected. Arrhythmia detection is a function of the telemetry receivers (Model ORG-9700 Multiple Patient Receiver, per 510k K071058 Commercial distribution certification dated June 29, 2007) transmitter (Model ZS-940PA, per 510(k) K043517 Commercial Distribution certification dated February 3, 2005). Alarm determination can be configured to be performed by either the Prefense EDNS-9000 Series Central Nurse Station or by the telemetry receivers (Model ORG-9700 Multiple Patient Receiver, per 510k K071058 Commercial distribution certification dated June 29, 2007) transmitter (Model ZS-940PA, per 510(k) K043517 Commercial Distribution certification dated February 3, 2005).

- **Intended Use**
  The Prefense EDNS-9000 Series Central Nurse Station is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility.
  The Prefense EDNS-9000 Series Central Nurse Station will display and record physiological data from up to forty telemetry receivers/transmitters and generates an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected. Arrhythmia detection is a function of the telemetry receivers/transmitters. Alarm determination can be configured to be performed by either the Prefense EDNS-9000 Series Central Nurse Station or by the telemetry receivers/transmitters.

- **A summary of the technological characteristics of the device compared to the predicate device:** The new device consists of a software change to the predicate device (EDNS-9000) that allows alarm determination to be performed by the EDNS 9000 or the ORG 9700A
    - The technical characteristics of the EDNS-9000 predicate and the new EDNS-9000 are identical with the exception that the new device can perform alarm detection. The alarm detection feature of the predicate ORG-9700A is available in the new device EDNS-9000

To date, no special controls or performance standards are known or established for this device.

The device is not sterile.

The device does not contact patient. Therefore, no good laboratory practice studies were required per 21 CFR 58. There is minimal contact of the device (CPU and Display) with the user so the ISO 10993 standard was reviewed and based on the flow chart in Annex B, the material used on the CPU and display hardware are commercially available and the MSDS data from the manufacture confirms that the standards requirement for ISO 10993 for this device have been met.

Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

The device was subjected to the following non-clinical tests; electromagnetic, environmental, safety and performance testing. These test verified the proper operation of the device. Design validation confirmed the operation of the software and hardware of the device is in accordance to the design specifications.

Therefore based on the above, Nihon Kohden believes that the Prefense EDNS-9000 Series Central Nurse Station with Software Update is substantially equivalent to the predicate device, Nihon Kohden Prefense EDNS-9000 Series Central Nurse and the ORG 9700A Multiple patient Receiver.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 17 2010

Nihon Kohden Corp.
c/o Mr. Steve Geerdes
Director QA/RA
90 Icon Street,
Foothill Ranch, CA 92610

Re: K102106
Trade/Device Name: Nihon Kohden Prefense EDNS-9000 Series Central Nurse Station
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DRG
Dated: November 19, 2010
Received: November 23, 2010

Dear Mr. Geerdes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

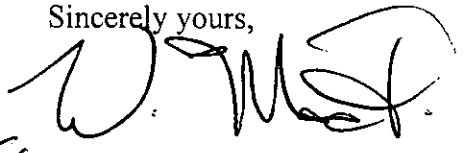
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): ___K102106___

Device Name: ___ Prefense EDNS-9000 Series Central Nurse Station___

Indications for Use:

The Prefense EDNS-9000 Series Central Nurse Station is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility.
The Prefense EDNS-9000 Series Central Nurse Station will display and record physiological data from up to forty telemetry receivers/transmitters and generates an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected. Arrhythmia detection is a function of the telemetry receivers/transmitters. Alarm determination can be configured to be performed by either the Prefense EDNS-9000 Series Central Nurse Station or by the telemetry receivers/transmitters.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K102106