

K972001

### 510(k) Summary

**Submitter's Name:** N.I. Medical, Ltd. JUL - 8 1997  
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**Contact Person:** Alexander Tsoglin  
Director of Research and Development

**510(k) Summary Date:** March 28, 1997

**Device Name:** NICaS™ Electrode

**Common Name:** Electrode for bipolar method of bioimpedance measurement

**Classification Name:**

**Predicate Devices:** With respect to indication for use:  
Nicolet Biomedical Instruments Velcro ground strap included in the  
NICaS™ 2001 510(k), (K942227)

With respect to materials and biocompatibility:  
Katecho, Inc. K-Defib/Pace Pediatric Electrode (K954505)

#### Device Description:

The NICaS™ Electrodes are fixed to intact skin of the arms and legs of a patient that is to be monitored for cardiac output. The electrodes employ a biocompatible conductive adhesive to maintain their position for up to 24 hours of continuous monitoring. As stated in the original submission, the electrodes conduct a 1.4 mA, 32.5 KHz current to the skin from the NICaS™ 2001 Noninvasive Cardio-Respiratory System (K942227) which uses the principle of bioimpedance to determine various cardiac parameters including cardiac output. The change from the strap type electrodes included in the original submission will permit longer term patient monitoring. The change in electrodes does not require any changes to the NICaS™ 2001 Noninvasive Cardio-Respiratory System itself. The electrodes continue to be attached to the two identified input connectors of the patient module. The patient module also connects with the computer.

The electrode design is similar to the Katecho, Inc. K-Defib/Pace Pediatric Electrode (K954505). The materials and manufacturing methods are the same, therefore no new biocompatibility issues

are raised. The only change is that the size and shape of the electrode has been modified for ease of use in the clinical setting.

**Intended Use:**

The NICaS™ Electrode is used only in conjunction with the NICaS™ 2001 and all other NICaS™ devices .

The function of the NICaS™ Electrode is unchanged from that of the Nicolet Biomedical Instruments Velcro ground strap in the original NICaS™ 2001 cardio-respiratory system, (510(k) K942227) submission, namely, to transmit electrical signals to and from the skin and the NICaS™ cardio-respiratory system.

**Comparison of Technological Characteristics:**

Both the NICaS™ Electrode and the Katecho, Inc. K-Defib/Pace Pediatric Electrode are constructed from identical foam base, tin laminate conductor and a biocompatible conductive gel materials. The NICaS™ Electrode is a different shape and smaller size than the Katecho, Inc. K-Defib/Pace Pediatric Electrode. The principles of operation of the NICaS™ 2001 cardio-respiratory system remain unchanged and the electrical current carried by the NICaS™ Electrode is identical to that carried by the Nicolet Biomedical Instruments Velcro ground strap.

**Safety and Effectiveness Information:**

The NICaS™ 2001 cardio-respiratory system was designed to meet the IEC 601-1-1 and UL 544 medical safety standards. It was tested and approved by TÜV. In addition, the electrodes conform to ANSI/AAMI EC12-1991 paragraph 3.2.2.1 and ANSI/AAMI EC12-1991 paragraph 3.2.1 standards.

**Data:**

The performance characteristics of the NICaS™ Electrode have been measured over the full 24 hour recommended period of use in a study employing volunteers. This study was performed by N.I. Medical. It demonstrated that cardiac output data gathered at several points during the 24 hour period are stable throughout the observation period. A second study performed by N.I. Medical on normal volunteers confirmed that cardiac output data gathered using the new electrodes closely correlated with data obtained using the Nicolet Biomedical electrodes.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Barry Sall, R.A.C.  
PAREXEL International Corporation  
1601 Trapelo Road  
Waltham, Massachusetts 02154

Re: K972001  
NICaS™ 2001 Cardio-Respiratory System  
Regulatory Class: II (two)  
Product Code: 74 DRX  
Dated: May 29, 1997  
Received: May 30, 1997

JUL - 8 1997

Dear Mr. Sall:

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 (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.

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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

510(k) Number (if known): K972001

Device Name: NICaS™ 2001 cardio-respiratory system

Indications For Use:.....

The NICaS™ electrode is used only in conjunction with the NICaS™ 2001 and all other NICaS™ devices.

The function of the NICaS™ electrode is unchanged from that of the Nicolet Biomedical Instruments Velcro ground strap in the original NICaS™ 2001 cardio-respiratory system, (510(k) K942227) submission, namely, to transmit electrical signals to and from the skin and the NICaS™ 2001 cardio-respiratory system.

The indications for use of the NICaS™ 2001 cardio-respiratory system remain unchanged from those included in the original NICaS™ 2001 cardio-respiratory system, (510(k) K942227), namely, monitoring hemodynamic parameters including stroke volume, stroke index, heart rate, cardiac index, cardiac output, and total peripheral resistance; and the ventilatory parameter, respiratory rate. The device is intended for use in male and female patients with cardiovascular disorders including:

- patients undergoing cardiac catheterization
- cardiac surgery patients
- patients in intensive and cardiac care units
- patients in rehabilitation centers

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh  
 (Division Sign-Off)  
 Division of Cardiovascular, Respiratory,  
 and Neurological Devices  
 510(k) Number K972001

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional format 1-2-96)