K080941

510(K) Summary

Submitter:

N. I. Medical, Ltd.
3 Ein Chay Street
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Israel

JUN 18 2009

Contact Person:

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Date Prepared: June 12, 2009

Device Trade Name: NICaS CS Bioimpedance Cardiac Analyzing Measuring System

Common/Usual name: Bioimpedance Cardiac Analyzing measuring System

Classification name: Impedance Plethysmograph

Predicate Devices: NICaS 2004 Slim Noninvasive Cardio-Respiratory System (510(k) number K070500) and the, BIO Z HemoDynamic Monitor (510(k) number K070156)

Device Description:

The NICaS (non-invasive cardiac system) CS is a CD-ROM shaped device which replaces the actual CD-Rom of a laptop computer. It is used for noninvasive cardiac diagnostic purposes.

The NICaS (non-invasive cardiac system) CS is an impedance device which is unique in its use of a laptop computer *as* part of a technology for non-invasively measuring the cardiac output and its derivatives. The NICaS is also unique in that it is the only method of impedance cardiography (ICG) which utilizes only two pairs of impedance electrodes, placed on two limbs, preferably one pair on the wrist, and the other on the contra-lateral ankle. This type of electrical surveillance is called regional ICG, or RIC.

The NICaS is a tetrapolar apparatus which operates by an alternating current of 1.4 mA and 32 kHZ.

The principle of this technology is based on the fact that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion (pulsation), an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured. This systolic resistance (impedance) change is termed ΔR, and the baseline body resistance is R (Ω).

The analog resistance signals are received by the device, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are digitized and analyzed via mathematical algorithms.

Indications for Use:

The NICaS CS is intended to monitor and display a patients hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, total peripheral resistance, and the Granov-Goor Index), in males and females with known or suspected cardiac disorders needing cardiac assessment.

Statement of Technical Comparison;

The NICaS CS bioimpedance cardiac analyzing measuring system is substantially equivalent to the NICaS 2004 Slim non-invasive cardio-respitory system which was cleared under 510(k) number K070500. Both of these devices were developed by and are manufactured for N.I. Medical, Ltd., Israel. Both devices are also used for noninvasive cardiac diagnostic purposes. The only difference between the two devices is that in addition to the indications for use in the NICaS 2004 Slim, the NICaS CS measures the Granov-Goor Index.

The principle of the technology used by both devices is based on the fact that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion (pulsation), an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured. This systolic resistance (impedance) change is termed ΔR, and the baseline body resistance is R (Ω).

The analog resistance signals are received by the devices, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are digitized and analyzed via mathematical algorithms. The data are portrayed on the computers screen

The following table lists the similarities and differences between the devices:

Attribute	Predicate Device NICaS 2004 Slim	NICaS CS

1. Computer Connection	Fits into the computer CD-ROM area	Fits into the computer CD-ROM area
2. Leads	Tetrapolar (4 leads) with snaps	Tetrapolar (4 leads) with snaps
3. Body connection	ECG snap electrodes	ECG snap electrodes
4. Mathematical data analysis	Two algorithms	Three algorithms. - Adds measurement of the Granov-Goor Index

FUNCTIONAL SUBSTANTIAL EQUIVALENCE (measurements)

The measurement of the Granov-Goor Index by the NICaS CS and the use of these measurements is substantially equivalent to the use and measurement of some of the parameters presented by the BIO Z HemoDynamic Monitor and Philips 12-lead ECG in 510(k) number K070156.

The following is a copy of the BIO Z Hemodynamic Monitor's indications for use in 510(k) number K070156 and a discussion detailing why the measurement of the Bio Z Systolic time Ratio (STR) is the same as the Granov-Goor Index measurement in this 510(k):

"For the ICG function:

The BioZ Dx Hemodynamic Monitor is intended to monitor and display a patient's hemodynamic parameters. These parameters include:

Heart Rate (HR
Systolic Blood Pressure (SBP)
Diastolic Blood Pressure (DBP)
Mean Arterial Blood Pressure (MAP)
Stroke Index (SI)
Stroke Volume (SV)
Cardiac Index (CI)
Cardiac Output (CO)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
Left Cardiac Work (LCW)
Acceleration Index (ACI)
Velocity Index or Index of Contractility (VI, IC)

Thoracic Fluid Content (TFC)
Base Impedance (TFI or Z0)
Thoracic Fluid Content Index (TFCI)
Systolic Time Ratio (STR)
Systolic Time Ratio Index (STRI)
Pre-Ejection Period (PEP)
Left Ventricular Ejection Time (LVET)
Total Arterial Compliance (TAC)
Total Arterial Compliance Index (TACI)
Left Stroke Work Index (LSWI)
Heather Index (HI)
Q -C Interval (QC)
Left Cardiac Work Index (LCWI)
Electrocardiograph (ECG)
Systemic Stroke Resistance Index (SSRI or SSVRI)
End Diastolic Volume (EDV)
End Diastolic Index (EDI)

For the optional 12-lead ECG function:

Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms."

The BioZ and the NICaS CS utilize precisely the same technologies for assessment of the electrical signal which is generated by the body during the contraction of the heart. The only difference between these two technologies is that for the BioZ, the electrodes are placed on the chest wall, and in case of the NICaS, the electrodes are placed on the two limbs, preferably on one wrist and one ankle. The consequences of the different locations of the electrodes are what lead to the differences in the formulae and the performance of these two tools.

The three parameters in the above mentioned BioZ list which are relevant to our Granov-Goor Index measurement, are the Systolic Time Ratio (STR), the Pre-Ejection Period (PEP), and the Left Ventricular Ejection Time (LVET).The STR comprises the following formula PEP/LVET. The PEP (Pre-Ejection Period), also called the isovolumetric contraction, is the time interval between the beginning of the cardiac contraction and the beginning of the blood ejection from the heart into the circulation The average duration of the PEP in the normal heart is in the range of 95 milliseconds (msec).In the presence of heart failure (HF), like in cases of Left Ventricular Systolic Dysfunction (LVSD), there is a prolongation of the PEP by about 20-60% [1, 2]. As a result of the impairment of the cardiac function, there is also a reduction in the amount of blood ejected by the cardiac contraction into the circulation, with a consequential diminution of the time duration of the LVET by 30-100 m/sec from the average normal value of 400 m/sec.

Although these two Systolic Time Intervals (STI), the PEP and the LVET, independently correlate well with reductions in cardiac functions measured by the LV Ejection Fraction (EF), the combined formula of the PEP/LVET, which is called the Systolic Time Ratio (STR), provides a more reliable indication about the probability of the presence of heart failure than each of the two alone

Our algorithm utilizes the ejection time parameter, called α, but instead of assuming that prolongation of PEP results in a reduced heart function we actually check the outcome volume by using parameters which are derived from impedance changes ($\Delta R/R$) which is similar to the signals used by BioZ. Since this measurement is made by the same impedance principal as the BioZ, the measurements of the STRs by the BioZ and the GGI by the NICaS CS are similar medical parameters.

There is a second common denominator between the NICaS CS and the BioZ, where the Granov-Goor Index is medically substantially equivalent to the Heather Index (HI). Both consist of two parameters: an impedance parameter, $\Delta R/R$ in GGI, versus dZ/dt(first derivative of the ΔR) in the HI; and time, α in the GGI, versus QZi in the HI.

As to the HR, the Heather Index provides information about a single heart beat, whereas the information given by the GGI is per minute because it is multiplied by the HR.

Hence, the NICaS CS measurement of the Granov-Goor Index is medically substantially equivalent to the STR and the Heather index (HI) in the BioZ indications for use.

Non-clinical Testing:

The NICaS 2004 Slim was tested and found to comply with the requirements of IEC 60601-1-1.These data were included in 510(k) number K070500. Since there is no change in the device, except for the software, the data are included in this 510(k) by reference.

Clinical Testing:

Validation of the performance of the new algorithm in the NICaS CDS device was attained by a Helsinki-approved clinical trial of 60 consecutive studies. Comparisons were made between the assessment of left ventricular dysfunction as well as of normal function, which were determined by the NICaS and by a gold standard technology, 2-Dimensional Echo-Cardiography.

(Please include 510(k) number here: K080941)

HFZ #	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
Z-450	Forrest	6/12/09						

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
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Drafted by Shawn Forrest on 6/12/09
Boilerplate Last Updated: 6/3/09 – Brandi Stuart

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2009

NI Medical, Inc.
c/o Mr. James Collie
Consultant
J. R. Collie Associates, Inc.
414 Maryjoe Way
Warrington, PA 18976

Re: K080941
Trade Name: NICaS CS
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: April 23, 2009
Received: April 24, 2009

Dear Mr. Collie:

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K080941

Device Name: NICaS CS

Indications for Use:

The NICaS CS is intended to monitor and display a patients hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, total peripheral resistance, and the Granov-Goor Index), in males and females with known or suspected cardiac disorders needing cardiac assessment.

Prescription Use YES (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080941