SEP 1 4 2004

ZOE™ Fluid Status Monitor

510(k) SPECIAL PREMARKET NOTIFICATION SUMMARY

- **Device Trade or Proprietary Name:** **ZOE™ Fluid Status Monitor**
- **Common / Classification Name:** **Impedance Plethysmograph**
- **Class:** **Class II**
- **Regulation Number:** **870.2770**
- **Product Code:** **DSB**
- **Labeling:**

  Federal (United States) Law restricts this device to sale by or on the order of a physician or licensed healthcare professional.

- **Predicate Device for Substantial Equivalence Comparison:**

  The ZOE™ Fluid Status Monitor, also referred to as ZOE or Zoe in the rest of this document, is claimed to be substantially equivalent to the following currently marketed Predicate Device and currently being marketed by NMT, LLC:

Manufacturer	Device Name	510-K Number	Decision Date
Renaissance Technology, Inc.	IQ System™	K922218	December 08, 1992
Renaissance Technology, Inc.	IQ System™	K981720	February 08, 1998

- **Device Description:**

  The ZOE™ Fluid Status Monitor is a non-invasive, battery powered thoracic base impedance monitor designed as an 'early warning' monitor for determining changes in the fluid status of patients with fluid management problems.

  The ZOE works by applying a minimal current to the patient. measuring electrical impedance changes throughout the thorax as aortic blood flow increases and decreases in response to each heartbeat. Base Impedance also known as Z_o, decreases when fluid increases and rises when less fluid exists in the chest. This device incorporates a proprietary algorithm to calculate the Z_o value.

  The ZOE is designed for use with disposable, self-adhesive silver / silver chloride electrodes that are readily available / commercially approved within the United States for other approved cardiovascular monitoring systems.

- **Indications for Use Statement:**

The ZOE™ Fluid Status Monitor is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary Artery Disease related event
- Suffering from Recurrent Dehydration

- **Contraindications for Use**

The ZOE™ Fluid Status Monitor is contraindicated for use with patients:

- With allergies to electrode hydrogel
- Skin sensitivities to electrode hydrogel
- Skin breakdown in areas on the chest where ZOE electrode placement is required.

- **Clinical Performance Data**

Clinical performance data has been submitted.

- **Rationale for Substantial Equivalence**

1. The ZOE™ Fluid Status Monitor patient interface design is very similar to the predicate device [IQ System (Impedance Plethysmograph Monitor {DSB}) already approved by the FDA and currently being marketed by NMT, LLC]

2. The INTENDED USES and the OPERATING PRINCIPLES (i.e. Effectiveness) of the ZOE™ Fluid Status Monitor are the **SAME** as the Zo measurement function of the predicate device.

3. The OPERATIONAL FEATURES of the ZOE™ Fluid Status Monitor are the **SAME or SIMILAR** to those offered by the predicate device

4. The SAFETY FEATURES of the ZOE™ Fluid Status Monitor are the **SAME or very SIMILAR** to those offered by the predicate device.

Therefore, in summary, the ZOE™ Fluid Status Monitor is substantially equivalent to the Zo measurement feature in the identified predicate device that has previously been allowed for commercial distribution in the United States.

• **Safety and Effectiveness**

The ZOE™ Fluid Status Monitor complies with the electrical standards of the Underwriters Laboratories UL 2601-1 / CSA C22.2 No. 60601 and has passed an inspection to these standards by an independent testing house. The ZOE underwent independent scrutiny and testing to assess the overall electrical safety and EMI safety. The ZOE met all electrical and electromagnetic compatibility (EMI) safety requirements set forth in the European national Safety Requirements LVD Low voltage Directive testing to Safety of Medical Devices EN 60601-1:2003, EMC testing to Emissions / Immunity Requirements for EMC/EMI requirements for Medical Devices EN 60601-1-2 which reasonably assures the device is safe when used as directed for its prescribed intended use.

The ZOE does not raise any new issues of safety, effectiveness or performance of the device when compared to the existing predicate device.

• **Conclusions**

The data submitted in this 510(k) Premarket Notification, for the ZOE Fluid Status Monitor demonstrates that this product is substantially equivalent with respect to the indications for use, operating principles, operational features, and safety features to the identified legally marketed predicate device. With the information provided, the safety and effectiveness of the product can be reasonably assured, and we believe that this device clearly meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(k) guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2004

Noninvasive Medical Technologies, LLC
c/o Mr. Alden Kay
Consultant
4367 Tuolumne Place
Carlsbad, CA 92008-7924

Re: K042113
Trade Name: ZOE™ Fluid Status Monitor
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Code: DSB
Dated: August 3, 2004
Received: August 5, 2004

Dear Mr. Kay:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

K042113

510(k) Number (if known): K042113

Previously approved as: **K981720**

Device Name: **"ZOE™ Fluid Status Monitor"** Impedance Plethysmograph

Indications For Use:

As with the predicate devices indicated in this submission (cardiac monitors employing impedance plethysmography {DSB}):

The ZOE™ Fluid Status Monitor is intended for:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary Artery Disease related event
- Suffering from Recurrent Dehydration

The ZOE™ Fluid Status Monitor is contraindicated for use with patients:

- With allergies to electrode hydrogel
- Skin sensitivities to electrode hydrogel
- Skin breakdown in areas on the chest where ZOE electrode placement is required.

This device is intended for use by qualified health care practitioners, under the direction of a physician, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

(optional format: 1-2-96)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042113