JUL 2 5 2008

Exhibit #1

K073249

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is:_____.

1. **Submitter's Identification:**

Alan P. Schwartz
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, N.Y. 11021

Date Summary Prepared: July 17, 2008

2. **Sponsor Company Name/Address/Contact Person**

Solaris Medical Technology, Inc.
400 Oyster Point Blvd., Ste. 534
South San Francisco, CA 94080
Tel: (415) 221-4350
Fax: (415) 221-4360

Contact: Rachel Cheng
Position: Director, Regulatory Affairs

3. **Manufacturing Facility Name and Address**

Newtech, Inc.
R1-B1, Hi-Tech Industrial Park
Nanshan District, Shenzhen
Guangdong 518057 P.R. China

4. **Name of the Device:**

SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories

5. Common or Usual Name:

Oximeter. Pulse
74 DQA. 21 CFR Part 870.2700

6. Predicate Device Information:

K# 001688, Datex-Ohmeda TuffSat 3000 Pulse Oximeter, Datex-Ohmeda Inc.

7. Device Description:

Purpose and Function of Device:

The subject SOLARIS NT1 and NT1A Handheld Pulse Oximeters measure pulse rate and oxygen saturation. The signals are converted into digital data and processed; the pulse oximeter examines the data and displays the data. The subject pulse oximeters also provide operating control for the user. The pulse oximeters are intended for use in spot checking; the NT1A model is intended to both spot check and perform continuous monitoring. The pulse oximeters can be used in hospital clinical areas such as general wards to provide additional information to the medical and nursing staff about the physiological condition of the patient. The subject devices are intended to be used under supervision by clinical personnel. The intended location of use is clinics.

The subject pulse oximeters provide a rapid indication of a patient's level of oxygenation which reflects the effective ventilation. The NT1A Pulse Oximeter with alarm allows continuous and instantaneous monitoring of SpO2 and both the NT1 and NT1A Pulse Oximeters reduce the need for arterial puncture and blood-gas analysis.

The subject pulse oximeters are composed of two boards, a main control board and a physiological singal processing board. The main control board is composed of a LED display and its control and driver, data memory, audio circuit, UART communication interface, and DC/DC circuits. The physiological processing board is composed of a SpO2 sensor control and IR/RED LEDs driver, data collection, signal processing algorithm execution, UART communication interface and DC/DC circuits.

The oximeter is housed in a single package. The main components of the assembly are listed as following

- Main Board
- SpO2 Module

- Key Pad
- Battery

8. Intended Use:

The SOLARIS NT1 and NT1A Handheld Pulse Oximeters with sensor accessories are non-invasive, spot-check, oxygen saturation and pulse rate monitors. They operate on battery power using SOLARIS reusable Sp02 sensors for pediatric and adult patients.

9. Comparison to Predicate Devices:

The basic intended use of the subject devices and Datex-Obmeda TuffSat 3000 Pulse Oximeter are the same:

1. Both the NT1 Pulse Oximeter and Datex-Ohmeda *TuffSat* 3000 Pulse Oximeter are non-invasive, spot-checking monitors. The difference between the NT1 and Datex-Ohmeda devices and the NT1A device is that in addition to being non-invasive spot-checking monitors, the NT1A device performs continuous monitoring.

2. The patient parameters for both the subject devices and Datex-Ohmeda TuffSat 3000 Pulse Oximeter are the same: oxygen saturation (SpO2), pulse rate (PR) and pulse strength.

3. The target populations range for both the subject devices and the Datex-Ohmeda Tuffsat 3000 Pulse Oximeter is the same: for pediatrics and adults.

Both the NT1 and NT1A Pulse Oximeters are substantially equivalent to Datex-Ohmeda TuffSat 3000 Pulse Oximeter. The pulse oximeters provide a means for interfacing with a patient and collecting parameter specific physiological signals. Then the signals are converted into digital data and processed, and the SpO2 and pulse rate values are calculated and displayed on LED screen.

10. Testing

Laboratory testing was conducted to validate and verify that the SOLARIS NT1

and NT1A Handheld Pulse Oximeters with Sensor Accessories met all design specifications and were substantially equivalent to the predicate device, Datex-Ohmeda TuffSat 3000 Pulse Oximeter. SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories have also been tested to assure compliance to the requirements of various published standards, including IEC60601-1, IEC60601-2, IEC60601-1-4, EN865, EN475, and ISO14971.

11. Conclusions:

The conclusions drawn from clinical and laboratory testing of the SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories demonstrates that the device is as safe, as effective, and performs as well as the legally marketed predicate device, the Datex-Ohmeda TufSet 3000 Pulse Oximeter, K001688.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2008

Solaries Medical Technology, Incorporated
C/O Mr. Alan P. Schwartz
mdi Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K073249
Trade/Device Name: SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 7, 2008
Received: July 9, 2008

Dear Mr. Schwartz:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

Indications for Use

510(k) Number (if known): _____

Device Name: SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories

Indications For Use:

Solaris NT1 and NT1A Handheld Pulse Oximeters with sensor accessories are non-invasive spot-check, oxygen saturation and pulse rate monitors. They operate on battery power using SOLARIS reusable Sp02 sensors for pediatric and adult patients.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073249

Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)