MAR 1 2 2010

Exhibit #1

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: K092950

1. Submitter's Identification:

Susan Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd.
Great Neck, N.Y. 11021

Date Summary Prepared: September 22, 2009

2. Sponsor Company Name/Address/Contact Person

Solaris Medical Technology, Inc.
400 Oyster Point Blvd., Ste. 534
South San Francisco, CA 94080
Tel: (650) 588-3980
Fax: (650) 588-3988

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:**

K073249, SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories, Solaris Medical Technology, Inc.

7. **Device Description:**

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.

8. **Intended Use:**

The Solaris NT1 Handheld Pulse Oximeter with Sensor Accessories is a non-invasive spot-check, functional arterial oxygen saturation and pulse rate monitor. The device operates on battery power using SOLARIS reusable Sp02 sensors. The device is intended for pediatric and adult patients and can be used in hospital clinical areas by medical and nursing staff.

The Solaris NT1A Handheld Pulse Oximeter with Sensor Accessories is a non-invasive spot-check or continuous monitoring, functional arterial oxygen saturation and pulse rate monitor. The device has data storage and data transfer functionality via a USB hub. The device operates on battery power using SOLARIS reusable Sp02 sensors. The device is intended for pediatric and adult patients and can be used in hospital clinical areas by medical and nursing staff.

9. Comparison to Predicate Devices:

The modified SOLARIS NT1 and NT1A Handheld Pulse Oximeters with Sensor Accessories have the same "Indications for Use Statement" and are similar in design to our original 510(k) cleared device predicates.

Based on new market requirements for NT1 and NT1A Handheld Pulse Oximeters, we are adding USB hub, test data storage and output and external storage functions, making operation and data processing more convenient and allowing implementation of external database processing and third-party analysis.

Modifications made to the original device design (NT1 and NT1A) do not affect any change in structure and appearance. Design improvements on the hardware circuit and software has been made by adding USB hub, data storage and data output functions.

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. 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. Performance testing for the NT1A device was conducted to show that the accuracy and measurement range of the device is not affected by the device re-design. Performance testing documentation was included in the submission under "NT1A Sp02 Oximeter Testing Reports".

11. Conclusions:

The conclusions drawn from 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.

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

Solaris Medical Technology, Incorporated
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

MAR 12 2010

Re: K092950
Trade/Device Name: SOLARIS NT1 Handheld Pulse Oximeter with Sensor Accessories, SOLARIS NT1A Handheld Pulse Oximeter with Sensor Accessories
Regulation Number: 21CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 4, 2010
Received: March 5, 2010

Dear Ms. Goldstein-Falk:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

Indications for Use

510(k) Number (if known): _____

Device Name: SOLARIS NT1 Handheld Pulse Oximeter with Sensor Accessories

Indications For Use:

The Solaris NT1 Handheld Pulse Oximeter with Sensor Accessories is a non-invasive spot-check, functional arterial oxygen saturation and pulse rate monitor. The device operates on battery power using SOLARIS reusable Sp02 sensors. The device is intended for pediatric and adult patients and can be used in hospital clinical areas by medical and nursing staff.

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)

L Schultz

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K092950

Exhibit C

Indications for Use

510(k) Number (if known): _____

Device Name: SOLARIS NT1A Handheld Pulse Oximeter with Sensor Accessories

Indications For Use:

The Solaris NT1A Handheld Pulse Oximeter with Sensor Accessories is a non-invasive spot-check or continuous monitoring, functional arterial oxygen saturation and pulse rate monitor. The device has data storage and data transfer functionality via a USB hub. The device operates on battery power using SOLARIS reusable Sp02 sensors. The device is intended for pediatric and adult patients and can be used in hospital clinical areas by medical and nursing staff.

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)

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

510(k) Number: K092950