Exhibit#3 510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92

1.0 Submitter's Information

Establishment Registration Name:

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AUG 27 2013

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2.0 Device Information

Type of 510(k) submission:	Traditional
Device Common Name:	Pulse Oximeter and carbon dioxide detector
Trade Name:	NT1D Vital Signs Monitor
Model:	NT1D
Classification name:	Oximeter

Product Code:	DQA
Secondary Product Code	CCK
Classification:	Class II
Regulation Number	21 C.F.R. 870.2700

3.0 Predicate Device Information

1. TidalWave SP pulse oximeter / carbon dioxide monitor Models 710/715 (510(k) No. K032971), dated 8/26,2004 .
2. SOLARIS NT1 and NT1A Handheld Pulse Oximeter with sensor accessories (510(k) No. K073249), dated 7/25,2008
3. Capnostat 5 CO_2 Sensor (510(k) No. K042601), dated 11/19,2004, LoFlo C5 CO_2 Sensor, (510(k) No. K053174),dated 1/12,2006

4.0 Device description

NT1D Vital Signs Monitor provides:

- SpO_2 monitoring
- Pulse rate (PR) monitoring
- End tidal carbon dioxide ($EtCO_2$) monitoring
- Respiration rate (RR) monitoring
- CO_2 and SpO_2 waveform display
- Audible and visual physiological and technical alarms
- Trend graph and trend table review
- Alarm event records review
- History data storage
- Rechargeable batteries
- External power supply and charger

The monitor is intended for monitoring adult and pediatric patients in clinical environments where healthcare is provided by healthcare professionals.

The product is composed of monitor, SpO_2 sensor, Mainstream/Sidestream CO_2 sensor, charging base, USB Adapter and PC software.

➢ SpO_2 theory of operation

Pulse oximetry is based on two principles: (1).The oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (i.e. Spectrophotometry), and (2). The volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (i.e. plethysmography). A pulse oximeter determines SpO2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption

during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LEDs) in the oximetry probe serve as light sources; a photodiode serves as the photo detector.

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation .To identify the oxygen saturation of arterial bemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood volume and light absorption increase.

During diastole, blood volume and light absorption reach their lowest point .The monitor bases its SpO2 measurements on the difference between maximum and minimum absorption (i.e., Measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

The Pulse oximeter determines SpO2 and pulse rate by passing two wavelengths of light, one red and one infrared, through body tissue to a photodetector. During measurement, the signal strength resulting from each light source depends on the color and thickness of the body tissue, the probe placement, the intensity of the light sources, and the absorption of the arterial and venous blood (including the time varying effects of the pulse) in the body tissue. (Refer To Figure E3-1)

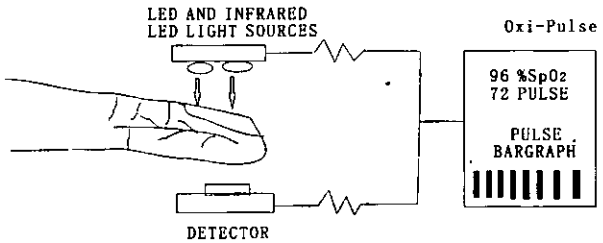

Figure E3-1: SpO2 Theory of Operation

The Pulse Oximeter processes these signals, separating the time invariant parameters (tissue thickness, skin color, light intensity, and venous blood) from the time variant parameters (arterial volume and SpO2) to identify the pulse rate and calculate oxygen saturation. Oxygen saturation calculations can be performed because oxygen saturated blood predictably absorbs less red light than oxygen depleted blood.

- **CO_2 theory of operation**

CO2 monitoring is to monitor the respiration of a patient by detecting the concentration of CO2 generated during respiration. The maximum concentration of CO2 at the end of exhalation is called End-Tide CO2 (EtCO2). The minimum concentration of CO2 at the end of inspiration is called Inspiration CO2 (FiCO2). CO2 is generated by cells in the body during metabolizing, and is breathed out via breathing system. The concentration of CO2 breathed out from the lung reflects directly the situation of metabolizing and breathing system. If the concentration of CO2 is high, it means that

metabolism is over active, such as blood poisoning or acute fever. If the concentration of CO2 is low, it is commonly due to a weak output ability of the heart, or the heartbeat stopped, or insufficient blood flow with less oxygen. Monitoring CO2 is used to warn the doctor of the abnormal breathing and metabolizing during anaesthesia.

The measurement value of CO2 is represented by a pressure level, with the unit: "mmHg" or "%". Generally, the maximum acceptable value is 38mmHg (5%) when air pressure is 760mmHg. The concentration of CO2 varies rapidly from 0% to 5%. To detect the concentration of CO2 accurately, the monitor needs to be very sensitive.

The monitor is used to measure EtCO2 and respiration rate of adult and pediatric patients.

5.0 Intended Use

NT1D is a handheld vital signs monitor that continuously monitors end tidal carbon dioxide ($EtCO_2$), respiratory rate (RR), oxygen saturation (SpO_2), and pulse rate. The unit is intended for monitoring only. The unit transfers history data to PC through a USB adapter. It is for use in any environment where continuous, noninvasive monitoring of these parameters is desired, including hospital and hospital-type facilities. The monitor is intended for use on adult and pediatric patients.

6.0 Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent(SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards.

No	Description
1	IEC60601-1:1988+A1:1991+A2:1995 Medical electrical equipment-Part1: General requirements for basic safety and essential performance
2	IEC 60601-1-2: 2007 Medical equipment-Part1-2: General requirements for safety-Collateral standard: Electromagnetic compatibility-Requirements and tests
3	ISO 9919:2005 Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
4	ISO 21647:2004 Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors. (Anesthesia)
5	FCC CFR 47 Part 15 Part C Radio frequency devices

7.0 Comparison to predicate device and conclusion

The proposed device NT1D vital signs monitor is substantially equivalent to systems marketed predicate devices. The intended use of NT1D vital signs monitor is same to TidalWave SP pulse oximeter. The design, the technological characteristics and the energy source are similar to TidalWave SP pulse oximeter. The comparison of technological characteristics between the proposed device and the predicate device in following table. Then NT1D has two parts, one is SpO_2 part, the other is CO_2 part. The SpO_2 part pulse oxygen sensor has three types, that is S400A ,S400P and T400A. S400A and S400P are the finger sensors of the predicate device NT1/NT1A which numbered K073249. The SpO_2 accuracy of NT1D is same as NT1&NT1A.The CO2 part is provided by Respironics Novametrix , which has gotten 510(k) No. The mainstream CO_2 sensor is Capnostat 5 CO2 Sensor, which 510(k) No. is K042601.The sidestream CO_2 sensor is LOFlo C5 CO2 Sensor, which 510(k) No. is K053174.
The notable difference between the NT1D and the predicate device is wireless transmission fuction. About this function, NT1D does the FCC test, and the test result is pass, which confirmed that it will no effect on performance.

Table E3-1 Comparison of the technological characteristics between the proposed device and the predicate device.

Comparison / Section	NT1D Vital Signs Monitor	TidalWave SP pulse oximeter / carbon dioxide monitor (Models 710/715)
Manufacturer	NEWTECH, INC	Respironics Novametrix, Inc
510(k) Number	Pending	K032971
Intended Use	The Newtech NT1D is a handheld vital signs monitor that continuously monitors end tidal carbon dioxide (EtCO2), respiratory rate (RR), oxygen saturation (SpO2), and pulse rate. The unit is intended for monitoring only. The unit	The intended use of the TidalWave SP (Models 710/715) is to provide short term monitoring of carbon dioxide and oxygen saturation during anesthesia / recovery, in the intensive care unit (ICU), and in Emergency Medicine /Transport or Respiratory care. Separate airway adapters are provided

	transfers history data to PC through a USB adapter. It is for use in any environment where continuous, noninvasive monitoring of these parameters is desired, including hospital and hospital-type facilities. The monitor is intended for use on adult and pediatric patients.	for pediatric/adult and neonatal/pediatric use. The TidalWave SP (Models 710/715) and its airway adapters and sensors are intended to be used by trained operators when capnographic and/or pulse oximetry monitoring is required in the judgement of a physician.
Range	0 ~100%	0 ~ 100%
Accuracy	±2% SpO2 (for 70 ~ 100% Spo2)(1SD) Unspecified for 0~69% SpO2	±2% SpO2 (for 70 ~ 100% Spo2)(1SD) Unspecified for 0~69% SpO2
Resolution	1%	1%
Audio	Pitch of pulse tone varies with Spo2 value	Pitch of pulse tone varies with Spo2 value
Principle	Using the time between successive pulses	Using the time between successive pulses
Range	30~250bpm	30~250 bpm
Accuracy	±1bpm or ±2% (take the larger one)	±1 % of full scale
Resolution	1bpm	1bpm
Principle	On-airway using an infrared absorption (IR) technique	On-airway using an infrared absorption (IR) technique
Range	0~150 mmHg	0 ~150 mmHg
Accuracy	±2 mmHg (0~40mmHg) ±5% of reading (41~70mmHg) ±8% of reading (71~100mmHg) ±10% (101~150mmHg)	±2 mmHg (0~40mmHg) ±5% of reading (41~70mmHg) ±8% of reading (71~100mmHg)
Resolution	1 mmHg	1 mmHg
Range	2~150bpm	0~150bpm
Accuracy	±1bpm	±1bpm
Resolution	1bpm	1bpm

External Power Supply Input	100～240 VAC,50/60Hz	100～250 VAC,50/60Hz
Battery	4 AA alkaline batteries or Ni-mh batteries	Nickel-metal-hydride or Standard AA lithium

Table E3-2 Comparison of the SpO2 Accuracy per Decade

Item		NT1D vital signs monitor with sensor S400A	TidalWave SP pulse oximeter / carbon dioxide monitor (Models 710/715)	NT1/NT1A Pulse Oximeter with sensor S400A (cleared **K073249**)
SpO_2 Accuracy	70%-80%	±2%	Unspecified	Unspecified
	80%-90%	±2%	Unspecified	Unspecified
	90%-100%	±2%	Unspecified	Unspecified
	70%-100%	±2%	±2%	±2%
Item		NT1D vital signs monitor with sensor S400P	TidalWave SP pulse oximeter / carbon dioxide monitor (Models 710/715)	NT1/NT1A Pulse Oximeter with sensor S400P (cleared **K073249**)
SpO_2 Accuracy	70%-80%	±2%	Unspecified	Unspecified
	80%-90%	±2%	Unspecified	Unspecified
	90%-100%	±2%	Unspecified	Unspecified
	70%-100%	±2%	±2%	±2%
Item		NT1D vital signs monitor with sensor T400A	TidalWave SP pulse oximeter / carbon dioxide monitor (Models 710/715)	NT1/NT1A Pulse Oximeter with sensor S400A (cleared **K073249**)
SpO_2 Accuracy	70%-80%	±2%	Unspecified	Unspecified
	80%-90%	±2%	Unspecified	Unspecified
	90%-100%	±2%	Unspecified	Unspecified
	70%-100%	±2%	±2%	±2%

Predicate devices TidalWave SP pulse oximeter / carbon dioxide monitor, and NT1/NT1A have no SpO_2 Accuracy description in the discrete range of 70%-80%, 80%-90% and 90%-100%. But all the NT1D SpO_2 Accuracy per decade is ±2%, same as SpO_2 Accuracy of 70%-100% of predicate devices. And NT1D and NT1/NT1A Pulse Oximeter share two same sensors S400P and S400A. Therefore, NT1D and predicate devices are substantially equivalent.

8.0 Clinical trial conclusion

NT1D vital signs monitor has two measurement modules, which are CO_2 module and SpO_2 module. The CO_2 module has gotten 510(k) number. Capnostat 5 CO_2 Sensor numbered K042601 and LoFlo C5 CO_2 Sensor numbered K053174. SpO_2 model includes three types of sensors, which are S400A, S400P, T400A. S400A and S400P are the finger sensors of the predicate device NT1/NT1A which numbered K073249. And clinical trial was conducted on NT1D with T400A sensor. The clinical trial was performed according to Annex EE.2 Procedure for invasive laboratory testing of ISO9919:2005 Medical electrical equipment— Particular requirements for the basic safety and essential performance of pulse oximeter equipment for the medical use on ten healthy volunteers, in Hypoxia Research Laboratory, University of California, San Francisco.

It is notable that for the T400A-160108 sensor, over half (60%) of the individual subjects, the sensors performed with ARMS <2.0%. The sponsor notes that their sensor validation studies were intellectually honest ones that pooled the data and did not seek a rationale to exclude outlier data except where specifically warranted (such as co-oximeter sample value outside the test range). Thus the pooled results for each sensor type, which includes some excellent performance [A_{RMS}<2.0] and some subjects with less accurate performance (A_{RMS}>3.0%, discussed in detail as requested) nevertheless meets the stated accuracy claims.

9.0 Conclusion:

The conclusions drawn from nonclinical test and clinical tests of the NT1D Vital Signs Monitor demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the TidalWave SP pulse oximeter / carbon dioxide monitor numbered K032971, NT1/NT1A Handheld Pulse Oximeter numbered K073249, Capnostat 5 CO_2 Sensor numbered K042601 and LoFlo C5 CO_2 numbered K053174.

10.0 Prepared Date: August 10, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2013

New Tech, Incorporated
C/O Ms. Diana Hong
General Manager
MID-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai China 200237

Re: K123797
Trade/Device Name: Vital Signs Monitor
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 24, 2013
Received: July 29, 2013

Dear Ms. Hong:

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 contact 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. 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,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Newtech, Inc.
Section I 《Indications for use statement》

Indications for use statement

510(k) Number (if known): K123797

Device Name: Vital Signs Monitor
Model: NT1D

Indications For Use:

NT1D is a handheld vital signs monitor that continuously monitors end tidal carbon dioxide (EtCO2), respiratory rate (RR), oxygen saturation (SpO2), and pulse rate. The unit is intended for monitoring only . The unit transfers history data to PC through a USB adapter. It is for use in any environment where continuous, noninvasive monitoring of these parameters is desired, including hospital and hospital-type facilities. The monitor is intended for use on adult and pediatric patients.

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
2013.08.27 09:26:23 -04'00'

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

510(k) Number: K123797