DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 2, 2016

Athena GTX
Sean Mahoney
V.P. Regulatory Affairs
5900 NW 86th Street, Suite 300
Johnston, IA 50131

Re: K160582
Trade/Device Name: WiCap™
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, CCK
Dated: August 4, 2016
Received: August 5, 2016

Dear Sean Mahoney:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 - Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below

510(k) Number *(if known)*

Device Name

WiCap™ Patient Monitor

Indications for Use *(Describe)*

The WiCap™ patient monitor is intended for the continuous or spot-check monitoring of carbon dioxide concentration of the expired (EtCO2) and inspired (FiCO2) breath and respiration rate (RR), and functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) measurements. Intended patient populations include: Adult, Pediatric, and Neonate patients. The device is for use in hospitals, healthcare facilities and clinics, nursing home facilities, and other healthcare environments. The WiCap™ patient monitor is to be used by trained healthcare providers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER 807.92(a)(1)]:

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Company Contact: Sean Mahoney (VP of Regulatory Affairs)
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Date Prepared: August 31, 2016

II. DEVICE [807.92(a)(2)]:

Trade Name:	WiCap™
Common Name:	Patient Monitor
Classification Name:	Oximeter (21 CFR 870.2700)
Device Class:	Class II
Product Code:	CCK, DQA
Basis for Submission:	New Device

III. PREDICATE DEVICE [807.92(a)(3)]:

Legally Marketed
(Predicate) Device: Oridion Medical 1987 Limited, Capnostream 20 (K060065)

IV. DEVICE DESCRIPTION [807.92(a)(4)]:

Device Identification
The WiCap Patient Monitor is a device that monitors physiological parameters associated with carbon dioxide gas and pulse oximetry.

Device Characteristics
The WiCap Patient Monitor is a multi-patient use non-sterile device. It utilizes embedded firmware. Patient applied parts are needed for physiological measurement and are provided via FDA cleared OEM accessories to the WiCap monitor.

Environment of Use
WiCap is intended to be used in hospitals, healthcare facilities and clinics, nursing home facilities, and other healthcare environments.

Section 5 – 510(k) Summary

Principle of Operation
WiCap uses non-dispersive infrared (NDIR) infrared spectroscopy to perform the capnography function (measuring carbon dioxide in exhaled breath (etCO2)). It is a side stream monitoring technique that utilizes a sample of the inhaled/exhaled patient's breath aspirated via a sample line (nasal cannula) to the CO2 OEM Module. The sample is drawn into the measurement module via DC driven pump.

Pulse oximetry measures the functional oxygen saturation of arterial hemoglobin. The patient's tissue is interrogated optically and the difference in the absorption of red and infrared light (spectrophotometry) by oxyhemoglobin and deoxyhemoglobin is analyzed. This measurement is also done non-invasively via light emitting diodes (LEDs) in the sensors applied to the patient.

Materials
The WiCap Patient Monitor enclosure is primarily plastic and does not contact the patient. The applied parts are OEM accessories that are FDA cleared and meet the biocompatibility requirements for intact skin contact.

Key Performance Specification
Key performance specifications are listed in the table in section VI below under capnography and pulse oximeter. Specific accuracy specifications for sensors that are compatible with the XPod pulse oximeter OEM module, are listed in the table below.

	Accuracy (± X digits)		
Sensor Model	**No Motion**	**Motion**	**Low Perfusion**
Adult/Pediatric			
8000AA-1, -2, -3	± 2	± 3	± 2
8000AP-1, -3	± 2	± 3	± 2
8000SS-1, -3 8000SM-1, -3 8000SL-1, -3	± 2	± 3	± 2
8000J-1, -3	± 2	- - -	± 2
8001J	± 2	- - -	± 2
8008J	± 2	- - -	± 2
8000Q2	± 3	- - -	± 2
8000R	± 2	- - -	± 2
6000CA, CP, CI	± 2	± 3	± 2
7000A, P, I	± 2	± 3	± 2
6500MA, SA	± 2	± 2	± 3
Neonate			
6000CN	± 3	- - -	± 2
7000N	± 3	- - -	± 2

V. INDICATIONS FOR USE [807.92(a)(5)]:

The WiCap patient monitor is intended for the continuous or spot-check monitoring of carbon dioxide concentration of the expired (EtCO2) and inspired (FiCO2) breath and respiration rate (RR), and functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) measurements. Intended patient populations include: Adult, Pediatric, and Neonate patients. The device is for use in hospitals, healthcare facilities and clinics, nursing home facilities, and other healthcare environments. The WiCap patient monitor is to be used by trained healthcare providers.

The Indications for Use statement for the WiCap device is not identical to the predicate device; however, the differences do not alter the key intended use of the device nor affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices measure the same physiological parameters, are to be used on the same patient populations and in the same environments and are for use by trained healthcare providers.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The WiCap Patient Monitor for monitoring end tidal CO2 and Pulse Oximetry employs the same technology principles as the predicate device. For CO2 measurements non-dispersive infrared (NDIR) infrared spectroscopy is used and for pulse oximetry functional oxygen saturation of arterial hemoglobin by analyzing the difference in the absorption of red and infrared light (spectrophotometry) by oxyhemoglobin and deoxyhemoglobin is used.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Uses OEM modules for Pulse Oximetry and Capnography (CO2 gas monitor)
- Same measurement techniques are used for both oximetry and capnography
- Both have alarms
- Both comply to the same industry and FDA recognized standards
- Both use rechargeable lithium based batteries

The following technological differences exist between the subject and predicate devices:

- Different OEM modules are used for Pulse Oximetry and Capnography (CO2 gas monitor)
- WiCap imparts a lower optical power to the patient
- WiCap is smaller and lighter
- WiCap has a lower battery/system voltage
- WiCap has been tested to more severe EMC requirements (Class B vs. Class A)

Section 5 – 510(k) Summary

The following is provided as a summary of how the technological characteristics of the device compare to the predicate device:

Product Element	WiCap	Capnostream20	Comments
Manufacturer	Athena GTX	Oridion Capnography Inc.	- - -
Model Number(s)	WiCap	Capnostream20	- - -
510(k) Number	Pending – new device	K060065	- - -
Physiological Parameters	carbon dioxide analyzer (EtCO2) and Pulse-Ox (SpO2 and Pulse Rate)	carbon dioxide analyzer (EtCO2) and Pulse-Ox (SpO2 and Pulse Rate)	Same
Patient Population	Adult, pediatric and neonate patients	Adult, pediatric and neonate patients	Same
Indications	The WiCap patient monitor is intended for the continuous or spot-check monitoring of carbon dioxide concentration of the expired (EtCO2) and inspired (FiCO2) breath and respiration rate (RR), and functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) measurements. Intended patient populations include: Adult, Pediatric, and Neonate patients. The device is for use in hospitals, healthcare facilities and clinics, nursing home facilities, and other healthcare environments. The WiCap patient monitor is to be used by trained healthcare providers.	The Capnostream20 is intended for CO2 and SPO2 indications. The Capnostream20 combined capnograph/pulse oximeter monitor is intended to provide professionally trained health care providers the continuous, non-invasive measurement and monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate, and for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2 and pulse rate). It is intended for use with neonatal, pediatric and adult patients in hospitals, hospital type facilities, intra hospital moves and home environments.	Substantially Equivalent
Environment of Use	Hospitals, healthcare facilities and clinics, nursing home facilities, and other healthcare environments	Hospitals, hospital type facilities, intra hospital moves and home environments.	Similar – Capnostream 20 includes home use.

Product Element	WiCap	Capnostream20	Comments
Compliance	IEC 60601-1:2012 Basic safety and essential performance IEC 60601-1-2:2007-03 and 2014-02 EMC IEC 60601-1-8:2012-11 Alarms ISO 80601-2-55:2011-12-15 Respiratory gas monitors ISO 80601-2-61:2011-04-01 Pulse oximeters IEC 60601-2-49:2011 Multifunction patient monitoring equipment	IEC/EN60601-1 UL 60601-1 CSA C22.2 No 601.1-M90 IEC/EN60601-1-2 Class A Radiated and Conducted Emission IEC 60601-1-8 (Audible and Visual Alarms) ISO 80601-2-55 (Capnography) ISO 80601-2-61 (Pulse Oximetry) IEC 60601-2-49 Multifunction patient monitoring equipment	Same
Capnography			
CO2, EtCO2, FiCO2 Range	0 to 150 mmHg, 0 to 19.7%	0-150 mmHg	Same
CO2 Accuracy	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading Above 80 breath per minute ± 12% of reading * NOTE: Gas temperature at 25°C	0-38 mmHg: ± 2 mmHg 39-150 mmHg: ± (5% of reading + 0.08 x (expected reading in mmHg –39mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for etCO2 values exceeding 18 mmHg.	Substantially Equivalent
Respiration Rate Range	2 to 150 breaths per minute (bpm)	0-150 bpm	Substantially Equivalent
Respiration Rate Accuracy	± 1 breaths per minute (bpm)	0-70 bpm: ±1 bpm 71-120 bpm: ±2 bpm 121-150 bpm: ±3 bpm	Substantially Equivalent
CO2 Alarms	No breath, etCO2 high, etCO2 low, FiCO2 high, FiCO2 low, RR high, RR low	No breath, etCO2 high, etCO2 low, RR high, RR low, IPI low	Same
Flow Rate	50 ml/min ±10 ml/min	50 (42.5 ≤ flow ≤ 65) ml/min, flow measured by volume	Substantially Equivalent

Product Element	WiCap	Capnostream20	Comments
Pulse-Oximeter			
SpO2 Measurement Range	0-100%	0-100%	Same
SpO2 Accuracy 70%-100% Adult & Pediatric No Motion Motion Low Perfusion Neonatal No Motion Motion Low Perfusion 0% - 69%	Varies per sensor type. Typical specs ± 2 digits ± 3 digits ± 2 digits ± 3 digits - - - ± 2 digits Unspecified	 ± 2 digits ± 3 digits Unspecified	Substantially Equivalent
Pulse Rate Range	30 to 250 beats per minute (bpm)	20-250 bpm	Substantially Equivalent
Pulse Rate Accuracy No Motion/Low Perfusion Motion	Varies per sensor type. Typical specs ± 3 digits ± 5 digits	± 3bpm	Substantially Equivalent
Alarms	SpO2 high, SpO2 low, Pulse Rate high, Pulse Rate low	Adjustable Alarm Limits SpO2 high, SpO2 low, Pulse Rate high, Pulse Rate low	Same
Measurement Technology			
CO2 Gas Detection OEM Module	Yes	Yes	Same
CO2 Measurement Technique	Non-dispersive infrared (NDIR) Infrared spectroscopy	Non-dispersive infrared (NDIR) Infrared spectroscopy	Same
Pulse-Ox OEM Module	Yes	Yes	Same
SpO2 Measurement Technique	Functional oxygen saturation of arterial hemoglobin	Functional oxygen saturation of arterial hemoglobin	Same
Pulse-Ox Sensors Red Wavelength IR Wavelength	LED 660 nanometers 910 nanometers	LED 660 nanometers 900 nanometers	Substantially Equivalent wavelengths.

VII. PERFORMANCE DATA [807.92(b)(1)]:

Biocompatibility
The WiCap patient monitor does not come in contact with the patient and was not tested for biocompatibility.

OEM cleared accessories are specified for use that contact the patient. The 510(k) clearance information was provided as part of this submission.

OEM in-cable oximeter has been tested for Biocompatibility since it may come in contact with the patient.

These products comply with ISO 10993 for intact skin contact for greater than 30 days and were tested for compliance to requirements for

- Cytotoxicity
- Sensitization
- Irritation

Industry Standards for Electrical Safety, EMC and Essential Performance
Testing of the WiCap Patient Monitor has been completed to verify compliance with FDA guidance, recognized national and international standards for electrical safety and performance for medical devices, and particular requirements applicable to this device including:

- Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff. Document issued on: March 4, 2013.
- IEC 60601-1:2012 Basic safety and essential performance
- IEC 60601-1-2:2007-03 and 2014-02 EMC
- IEC 60601-1-8:2012-11 Alarms
- IEC 60601-2-49:2011 Multifunction patient monitoring equipment
- ISO 80601-2-55:2011-12-15 Respiratory gas monitors
- ISO 80601-2-61:2011-04-01 Pulse oximeters
- IEC 60601-1-6: 2010 + IEC 62366:2007 Usability

Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Animal Study Data
None.

Clinical Study Data [807.92(b)(2)]:
OEM module and sensor clinical accuracy reports and manufacturer compliance statements were provided for the pulse oximeter parameter of the WiCap patient monitor that demonstrated compliance with the FDA Pulse Oximeter Guidance and ISO 80601-2-61 requirements. No further clinical testing was performed. Successful integration of the OEM module and sensor(s) was tested via a functional tester (pulse oximeter simulator) spanning the monitor's claimed range of pulse rate and saturation values.

SpO2 accuracy testing was conducted during induced hypoxia studies on healthy, non-smoking, light-to-dark-skinned subjects during motion and no-motion conditions in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the sensors were compared to arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples was measured over the SpO2 range of 70 – 100%. Accuracy data was calculated using the root-mean-squared (Arms value) for all subjects, per ISO 80601-02-61:2011, Standard Specification for Pulse Oximeters for Accuracy.

VIII. CONCLUSION [807.92(b)(3)]:

The results for all safety, compliance, and non-clinical performance testing demonstrates that the Athena GTX WiCap Patient Monitor is as safe and as effective as the above listed predicate device, has the same performance characteristics and is substantially equivalent to the above listed predicate device.