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TAB 5

510(K) SUMMARY

Official Contact

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Date of Submission January 10, 2012

Classification Reference 21 CFR 870.2700
21 CFR 870.2780

Product Code DQA
JOM

Common/Usual Name Oximeter

Proprietary Name CVInsight

Predicate Device(s) K102350, Nonin Medical 3150 Pulse Oximeter
K040589, Nonin Medical 9700 Pulse Oximeter with Pulse Wave form
K960884, LSI TeleTrens Model Number TM10
K853124, Novametrix Pulse Oximeter, Model 500

Reason for submission New Device

Indications For Use

The CVInsight system is comprised of a pulse oximeter and a software application installed and operating on a personal computer. The pulse oximeter device is indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and / or data collection and recording of patients who are well or

poorly perfused. The intended use environments are Hospitals, Medical Facilities, Ambulatory, Sub-Acute, and Sleep Studies. CVInsight measures, displays, and stores functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, and provides alarm functionality for these parameters.

Additionally, CVInsight provides a utility for recording trends of pulse rate, SpO2, and the percentage of change from a user-defined baseline value for values of pulse rate and pulse strength derived from the photoelectric plethysmograph waveform.

Device Description

The CVInsight system is comprised of a cleared pulse oximeter and software application operating on a personal computer and is intended to be a non-invasive tool in the physiological monitoring of adult and pediatric patients.

CVInsight wirelessly acquires and displays measures of pulse rate, functional oxygen saturation of arterial hemoglobin (SpO_2), and provides alarm functionality for these parameters. CVInsight provides factory default values or optional clinician determined threshold values in which triggers alarm conditions during CVInsight operation.

The device calculates percentage of change from a baseline value for the pulse rate and pulse strength values derived from the photoelectric plethysmograph waveform and graphically displays these values over time. The device also provides event indications based upon threshold values input by the clinician.

This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms. The device does not report any diagnosis but provides spot- checking and trending data only. It is the clinician's responsibility to make proper decisions based upon their experience and training.

Substantial Equivalence

CVInsight has the following similarities to the predicate devices:

- Same intended use.
- Same operating principle of
    - collecting data from a pulse oximeter/sensor
    - calculating data
    - displaying data

- graphically displaying data trends

- Same vehicle of transmission of data via a wireless connection.
- Similar that CVInsight provides factory default values or optional clinician determined threshold values which triggers alarm conditions during operation.

Intelomed, Inc. has determined that the CVInsight system does not raise new questions of safety and efficacy and has demonstrated that it is at least as safe and effective as the predicate devices as per the device comparison table below.

Features	Proposed Device (CVInsight)	K102350 Nonin Medical 3150 Pulse Oximeter	K040589 Nonin Medical Avant 9700 Pulse Oximeter	K960884 TeleTrens Model # TM10	K853124 Novametrix Pulse Oximeter, Model 500
Product Code	DQA (JOM)	DQA	DQA	DSI	JOM
Indications For Use	The CVInsight system is comprised of a pulse oximeter and a software application installed and operating on a personal computer. The pulse oximeter device is indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and / or data collection and recording of patients who are well or poorly perfused. The intended use environments are Hospitals, Medical Facilities, Ambulatory, Sub-Acute, and Sleep Studies. CVInsight measures, displays, and stores functional oxygen	Nonin's Model 3150 WristOx2 Pulse Oximeter is a small wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and /or data collection and recording of patients who are well or poorly perfused. The intended use environments are sleep and pulmonary rehab labs, surgical recovery, critical care, emergency room, long-term care, home use and mobile units.	The Nonin® Avant™ 9700 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult, pediatric, infant, and neonatal patients in hospitals, medical facilities, home care, and sub-acute environments. It may also be used in patient transport, sleep laboratories, and EMS environments. The Avant™ 9700 is intended for continuous monitoring and / or spot-checking of patients during both no motion and	The Teletrens is intended for use in the non-invasive monitoring of ECG, blood pressure, pulse rate, pulse oximetry, temperature and respiration in the hospital/clinic environment. The TeleTrens is intended to be used in accordance with accepted hospital and clinical protocols and instructions contained in this operators manual. Use of the TeleTrens for applications not specified in this manual may result in inaccurate patient information. Use of the TeleTrens with other than recommended or supplied accessories or parts may result in inaccurate patient information or damage to the monitor.	Pulse oximetry is a non-invasive means of obtaining information regarding oxygen saturation of arterial blood. Oxygen saturation monitoring is intended to be used in a variety of clinical situations including respiratory therapy, anesthesia, and the NICU.

Features	Proposed Device (CVInsight)	K102350 Nonin Medical 3150 Pulse Oximeter	K040589 Nonin Medical Avant 9700 Pulse Oximeter	K960884 TeleTrens Model # TM10	K853124 Novametrix Pulse Oximeter, Model 500
Product Code	DQA (JOM)	DQA	DQA	DSI	JOM
	saturation of arterial hemoglobin (SpO2) and pulse rate, and provides alarm functionality for these parameters. Additionally, CVInsight provides a utility for recording trends of pulse rate, SpO2, and the percentage of change from a user-defined baseline value for values of pulse rate and pulse strength derived from the photoelectric plethysmograph waveform.		motion conditions, for patients who are well or poorly perfused.	Federal law restricts this device to sale by or on the order of a physician.	
Prescriptive	Yes	Yes	Yes	Yes	Yes
Environment of Use	Hospitals, Medical Facilities, Ambulatory, Sub-Acute, Sleep Studies	Hospitals, Medical Facilities, Ambulatory, Sub-Acute, Sleep Study, Mobile Units	Hospitals, medical facilities, home care, sub-acute environments, patient transport, sleep laboratories, and EMS environments.	Hospital/Clinic Environment	Variety of clinical settings including respiratory therapy, anesthesia, and the NICU.
Patient Population	Adult and Pediatric	Adult and Pediatric	Adult, pediatric, infant, and neonatal	Unknown	Unknown
Software Driven	Yes	Yes	Yes	Yes	Yes
Measures	Functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate, photoelectric plethysmograph waveform, changes in pulse rate, changes in photoelectric plethysmograph	Functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate	Functional oxygen saturation of arterial hemoglobin (SpO_2), and pulse rate	ECG, blood pressure, pulse rate, functional oxygen saturation of arterial hemoglobin (SpO_2), temperature, and respiration.	Photoelectric plethysmograph waveform, oxygen saturation of arterial blood (SaO), and pulse rate, changes in photoelectric plethysmograph waveform amplitude

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Features	Proposed Device (CVInsight)	K102350 Nonin Medical 3150 Pulse Oximeter	K040589 Nonin Medical Avant 9700 Pulse Oximeter	K960884 TeleTrens Model # TM10	K853124 Novametrix Pulse Oximeter, Model 500
Product Code	DQA (JOM)	DQA	DQA	DSI	JOM
	waveform amplitude				
Components	Pulse oximeter, pulse oximeter sensor, CVInsight software, PC	Pulse oximeter sensor control unit, Pulse oximeter sensor	Desktop unit contains OEM III module used in Nonin Model 3150 sensor control unit, Pulse oximeter sensor, Avant 9700 display software	Pulse oximeter (Nonin Model 3150) sensor control unit, Pulse Oximeter Sensor, other non-pulse oximeter sensors, TeleTrens display software, PC	Desktop display
Communication Interface	Physiological data from sensor and pulse oximeter	Physiological data from sensor and pulse oximeter	Physiological data from sensor and pulse oximeter	Physiological data from sensor and pulse oximeter	Physiological data from sensor and pulse oximeter
Sensor Site Location	Forehead	Forehead, ear, or finger	Forehead, ear, or finger	Finger	Finger
Power	Battery for Sensor Control Unit, AC Power for PC	Battery	AC power	Battery for Pulse Oximeter, AC Power for PC	AC power with back-up battery
Alarms/Alerts	No alarms or alerts. Notifications are provided only	None	Yes	Yes	Notifications are provided only
Transmission of Sensor Data to PC	Data transmitted to PC via Bluetooth	Bluetooth transmission capability	Hardwired desktop system	Data transmitted to PC via Bluetooth	Hardwired desktop system

Performance Testing

Design verification tests were performed on the Intelomed CVInsight system as a result of the risk analysis and product requirements. Formal test protocols were written and executed to verify and validate the CVInsight system. All tests that were created for the CVInsight system had passing results with acceptance criteria successfully met, which demonstrates the safety & effectiveness of the device. Testing included software code reviews, software unit testing, software integration testing, bench verification testing, biocompatibility testing, environmental testing by analysis, user manual/labeling inspection, drawing inspections, and a clinical simulation (usability testing).

The following FDA Guidance Documents were used as part of this submission package.

- Pulse Oximeters Premarket Notification Submissions 510(k)s; Draft Guidance July 19, 2007
- Wireless Medical Telemetry Risks and Recommendations; September 27, 2000

- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 2005

In summary, the CVInsight System is substantially equivalent to the Nonin 3150 Pulse Oximeter cleared in K102350, Nonin 9700 Pulse Oximeter with Pulse Wave form cleared in K040589, LSI TeleTrens Model Number TM10 cleared in K960884, and Novametrix Pulse Oximeter, Model 500 cleared in K853124.

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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

SEP 4 2012

Intelomed, Inc.
c/o Mr. Jan Berkow
4284 Lampl Lane
Allison Park, PA 15101

Re: K120052
Trade/Device Name: CVInsight
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, JOM
Dated: July 20, 2012
Received: July 23, 2012

Dear Mr. Berkow

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

Enclosure

K120052

Indications for Use

510(k) Number (if known): _____

Device Name: CVInsight

Indications for Use:

The CVInsight system is comprised of a pulse oximeter and a software application installed and operating on a personal computer. The pulse oximeter device is indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is intended for spot-checking and / or data collection and recording of patients who are well or poorly perfused. The intended use environments are Hospitals, Medical Facilities, Ambulatory, Sub-Acute, and Sleep Studies. CVInsight measures, displays, and stores functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate, and provides alarm functionality for these parameters.

Additionally, CVInsight provides a utility for recording trends of pulse rate, SpO2, and the percentage of change from a user-defined baseline value for values of pulse rate and pulse strength derived from the photoelectric plethysmograph waveform.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/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 Cardiovascular Devices

510(k) Number K120052