DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 22, 2016

ivWatch, LLC
Jaclyn Lautz
Director of Regulatory Affairs and Quality Assurance
1100 Exploration Way, Suite 209
Hampton, Virginia 23666

Re: K162478
Trade/Device Name: ivWatch Model 400
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PMS
Dated: November 22, 2016
Received: November 28, 2016

Dear Jaclyn Lautz:

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,

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

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)*

K162478

Device Name
ivWatch Model 400

Indications for Use *(Describe)*

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear infusates, as an adjunctive device to the clinical evaluation in the healthcare setting of adults and pediatrics with peripherally-inserted catheters (PIVs). The device is indicated to assess patients for the subcutaneous infiltrations and extravasations but should not serve as a substitute for regular clinician assessment of the PIV site. The ivWatch Model 400 is intended for use by healthcare practitioners who have been trained in the use of the device.

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.

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ivWatch, LLC
1100 Exploration Way, Suite 209
Hampton, VA 23666

1.855.IVWATCH (489.224)
Fax: 757.224.5009
www.ivwatch.com

1 TRADITIONAL 510(K) SUMMARY

1.1 Administrative

Submitter Name	**ivWatch, LLC**
Applicant Address	1100 Exploration Way, Suite 209 Hampton, VA 23666
Phone	855-489-2824
Fax	757-224-5009
Primary Contact	Jaclyn Lautz, Ph.D., Director of Regulatory Affairs and Quality Assurance
Primary Contact Email	jaclyn.lautz@ivwatch.com
Primary Contact Phone	855-489-2824 x7023
Date Prepared	September 1, 2016

1.2 Subject Device

Trade Name	**ivWatch Model 400**
Manufacturer	ivWatch, LLC
510(k) Number	K162478
Device Class	II
Regulation Number	21 CFR 880.5725
Product Code	PMS (Peripheral Intravenous (PIV) Infiltration Monitor)
Classification Name	Infusion Pump

1.3 Predicate Device

Trade Name	**ivWatch Model 400**
Manufacturer	ivWatch, LLC
510(k) Number	K153605
Device Class	II
Regulation Number	21 CFR 880.5725
Product Code	PMS (Peripheral Intravenous (PIV) Infiltration Monitor)
Classification Name	Infusion Pump
Clearance Information	Design modification to the sensor cable sheathing of the ivWatch Model 400 (K142374)

1.4 Device Description

The ivWatch Model 400 is a medical device that provides continuous, non-invasive monitoring of human tissue adjacent to peripheral intravenous (PIV) insertion sites to aid in the early detection of infiltration and extravasation events. The ivWatch Model 400 consists of the ivWatch Patient Monitor (IPM), a reusable optical sensor cable and a single-use sensor receptacle.

The ivWatch Model 400 uses visible and near-infrared light to measure changes in the optical properties of the tissue near a PIV insertion site. The IPM contains an optical system that generates visible and near-infrared light signals that are sent through the optical sensor cable to the patient's skin. Simultaneously, the IPM measures the light reflected back through the optical sensor cable from the patient's skin. Measured changes between the emitted and reflected signals are processed by the ivWatch signal processing algorithm to determine if an infiltration event may have occurred. If changes in the optical properties of the tissue near the PIV insertion site are consistent with an infusate pooling in the subcutaneous tissue, the IPM emits audible and visual notifications intended to prompt the clinician to inspect the PIV site for a possible infiltration event.

1.5 Indications for Use

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear infusates, as an adjunctive device to the clinical evaluation in the healthcare setting of adults and pediatrics with peripherally-inserted catheters (PIVs). The device is indicated to assess patients for subcutaneous infiltrations and extravasations but should not serve as a substitute for regular clinician assessment of the PIV site. The ivWatch Model 400 is intended for use by healthcare practitioners who have been trained in the use of the device.

1.6 Comparison of the Subject Device to the Predicate Device

The subject device (ivWatch Model 400) is a modification to the legally marketed ivWatch Model 400 (K153605). The subject and predicate devices consist of the same components including the ivWatch Patient Monitor, a single-use sensor receptacle and a reusable optical sensor cable. The subject and predicate devices have the same intended use which is to aid in the detection of infiltrations and extravasations during peripheral IV infusion therapy. The subject and predicate devices have the same technological characteristics and principles of operation and there have been no significant changes to the design or materials of the subject device.

This submission includes labeling modifications to the indications for use and to the MR safety information and the addition of an RFID tag in the sensor cable to track sensor cable useful life. The indications for use has been revised to extend the target patient population from patients 18 years old or greater to a patient population including both pediatrics and adults. Clinical performance testing on the pediatric patient population under the age of 18 years demonstrates that the subject device is as safe and effective as the predicate device on patients 18

years old and greater. The MR safety information for the reusable sensor cable has been revised from "MR Unsafe" to "MR Conditional" on the sensor cable label. MR safety testing has been performed and demonstrates that the subject device is as safe and effective as the predicate device with the appropriate MR safety labeling. The RFID replaces a previously used USB method for tracking sensor cable useful life.

1.7 Performance Data

1.7.1 Sterilization and Shelf Life

The ivWatch sensor receptacle is the only component of the system supplied sterile. The sensor receptacle is sterilized by ethylene oxide (EO) in compliance with ISO 11135-1 and 10993-7. In addition, the sensor receptacle passed package and sterility testing in compliance with ISO 11607-1, ASTM F1140/F1140M-13, ASTM 2096-11 and ASTM D1469-14 supporting a 2-year shelf life.

The ivWatch sensor cable is designed to be cleaned between uses and cleaning and disinfection validation testing results passed all pre-defined acceptance criteria in accordance with AAMI-TIR-2010, AAMI TIR30-2011 and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.

1.7.2 Biocompatibility

The sensor receptacle and sensor cable sheathing are classified as prolonged duration (greater than 24 hours but less than 30 days) patient-contacting components. The sensor receptacle and sensor cable of the subject device have not changed compared to the predicate device. Therefore, the biocompatibility evaluation of the patient-contacting components conducted in accordance with the FDA Guidance Document "Use of the International Standard ISO 10993-1" and ISO 10993-1, ISO 10993-5 and ISO 10993-10 has not changed.

1.7.3 Electromagnetic Compatibility (EMC) and Electrical Safety

EMC and electrical safety testing were conducted on the subject device and results show that the ivWatch Model 400 is in compliance with the requirements of IEC 60601-1-2: 3rd Ed. 2007 and ANSI/AAMI ES60601-1:2005, 3rd E.

1.7.4 Magnetic Resonance (MR) Environment Testing

The ivWatch sensor cable has been assessed in the MR imaging environment in accordance with ASTM F2052-15, ASTM F2213-06-11, ASTM F2119-07-13, and ASTM F2182- 11a. MR compatibility testing results indicate that the sensor cable is MR Conditional.

1.7.5 Software Verification and Validation Testing

Software verification and validation testing for the ivWatch Model 400 was conducted and documented in compliance with 21 CFR 820 and in accordance with the FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and IEC 62304.

1.7.6 Performance Testing – Clinical

The predicate device submission included the clinical evaluation of the Model 400 in patients 18 years old or greater. The purpose of this 510(k) submission is to extend the Model 400 indications for use from patients 18 years old or greater to a target patient population including both pediatrics and adults. The pediatric IRB approved clinical study included in this submission demonstrates that the Model 400 is just as safe and effective in the pediatric population under the age of 18 years old as the use of the predicate device in the adult population. Safety and efficacy of the Model 400 has been demonstrated in accepted case studies representing an age distribution from 2 weeks to 17 years, patient weight measurements from 3.3 to 196.7 kg (mean, 34.5 kg), distributed skin pigmentations and similar proportions between male and female subjects.

The clinical validation studies in the pediatric population under the age of 18 years old assessed the performance (e.g. time difference between ivWatch detection and clinician detection of an infiltration, sensitivity and specificity) of the ivWatch Model 400. The ivWatch Model 400 detected 80.0% of infiltrations (95% CI [51.9% to 95.7%]) before detection by a clinician. There were no serious adverse events during the clinical study. Clinical results demonstrate that the ivWatch Model 400 is equivalent in the pediatric population as compared to the adult population.

1.7.7 Summary Table

Item	Predicate Device K153605	Subject Device K162478	Comparison
Intended use	The ivWatch Model 400 is designed to aid in the detection of infiltrations and extravasations during peripheral IV infusion therapy.	Same	Equivalent
Principles of operation	During IV fluid infusion, the ivWatch sensor transmits an optical signal through the tissue; the optical signal is altered if the IV fluid is accumulating in the tissue underneath the sensor, surrounding the intended intravenous administration route,	Same	Equivalent

	which may indicate that fluid is not being delivered to the intended intravenous administration route (i.e., if an infiltration or extravasation has occurred).		
Monitor	ivWatch patient monitor	Same	Equivalent
Single-use, sterile patient-contacting component used to secure the sensor-end of the sensor cable onto the patient's skin	ivWatch sensor receptacle	Same	Equivalent
Optical cable to transmit visible and near-infrared light signals between the monitor and the patient's skin	ivWatch sensor cable	Same	Equivalent
Power source	External power supply and internal lithium backup battery (compliant to IEC 62133:2012)	Same	Equivalent
Monitor MR safety	MR Unsafe	Same	Equivalent
MR safety labeling of sensor cable	MR Unsafe	MR Conditional Tested in compliance with ASTM F2052-15, ASTM F2213-06-11, ASTM F2119-07-13, and ASTM F2182-11a.	MR compatibility testing demonstrated that the sensor cable is MR Conditional.

Sterility of the ivWatch sensor receptacle	Sterilized by ethylene oxide (EO) in compliance with ISO 11135-1. Sterilant residuals pass the acceptance criteria in compliance with ISO 10993-7.	Same	Equivalent
ivWatch sensor receptacle shelf life	2 years Tested and passed all acceptance criteria in compliance with ISO 11607-1, ASTM 2096-11 and ASTM 2096-11.	Same	Equivalent
Biocompatibility of prolonged patient-contacting components (Sensor receptacle and sensor cable)	Tested and passed all biocompatibility acceptance criteria for prolonged intact skin contact in compliance with ISO 10993-1, ISO 10993-5 and ISO 10993-10.	Same	Equivalent
Reprocessing of the ivWatch sensor cable	Cleaning and low-level disinfection testing passed all acceptance criteria in accordance with AAMI-TIR-2010, AAMI TIR30-2011 and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.	Same	Equivalent
Sensor Cable Use limit	240 hours Sensor cable life is tracked with a USB key tethered to sensor cable.	240 hours Sensor cable life is tracked with RFID communication between RFID chip embedded in sensor cable	RF wireless testing and results are in compliance with IEC 60601-1-2:3rd Ed. 2007 and FCC Part

		strain relief and the optics board in the IPM.	15.225 and 15.702
Electromagnetic compatibility	Tested in compliance with no deviations from IEC 60601-1-2: 3rd Ed. 2007	Same	Equivalent
Electrical safety	Tested in compliance with no deviations from ANSI/AAMI ES60601-1:2005, 3rd ed. (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance); IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	Same	Equivalent
Radiofrequency wireless testing	n/a	Tested in compliance with no deviations from IEC 60601-1-2: 3rd Ed. 2007 and FCC Part 15.225 and 15.207	The RF communication frequency between the ISO 15693 tag and antenna inside the patient monitor is not adjustable and does not transmit patient data. Testing demonstrates that the RF communication is as safe as the predicate device.
Performance testing – Clinical	Age: Patients 18 years old or greater Skin color: Light,	Age: Pediatrics from birth up to and including 17	The patient population of the subject

target patient population	medium and dark PIV site: Hand and forearm	years old Skin color: Light, medium and ark PIV site: Hand, forearm, antecubital fossa, leg and foot	device compared to the predicate device differs in age to support safety and efficacy in the pediatric population.
Performance testing – Clinical results	***Sensitivity:*** 96.4% of infiltrations (95% CI [91.4% to 98.7%]) were detected in under 10 cc of fluid ***False notifications:*** A false positive notification occurred approximately once every 4 days.	***Time difference between ivWatch and clinician detection of infiltration:*** Red Check IV notification issued on average 29.8 hours prior to the clinician detection, 95% CI [14.8, 48.8 hours]. ***Sensitivity:*** 78.3% of infiltrations (95% CI [56.5 to 92.5%]) were detected prior to the clinician diagnosing the infiltration in the blinded non-alarming group. ***False notifications:*** A false positive notification occurred approximately once every 4 days. A false positive notification occurred approximately once every 10 days if notifications	The clinical performance data of the Model 400 support the safety and efficacy in the pediatric patient population (from birth up to and including 17 years old) as compared to the clinical performance data in patient's 18 years or greater. The clinical evaluation demonstrates that the ivWatch Model 400 is substantially equivalent to the predicate device submission.

		related to painful IV flushes and device-related issues are excluded.	
Performance testing – Clinical adverse events	There were no serious adverse events during the clinical study.	There were no serious adverse events during the clinical study.	There are no new safety issues associated with the use of the device in pediatrics.

1.8 Conclusions

The technological characteristics and principles of operation of the ivWatch Model 400 and the predicate device are the same. The clinical data provided in the submission supports the expansion of the indications for use to now include the pediatric patient population.

The results of the clinical study and performance testing indicate that the ivWatch Model 400 is substantially equivalent to the ivWatch Model 400 (K153605). The ivWatch Model 400 performs as intended and is substantially equivalent to the legally marketed predicate device.