DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 11, 2016

ivWatch, LLC
Ms. Jaclyn Lautz
Director of Regulatory Affairs and Quality Assurance
469 Mclaws Circle
Williamsburg, Virginia 23185

Re: K153605
Trade/Device Name: ivWatch Model 400
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: PMS
Dated: January 12, 2016
Received: January 14, 2016

Dear Ms. 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 yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
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)*
K153605

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, uncolored infusates, as an adjunctive device to the clinical evaluation in the hospital setting of patients 18 years old or greater with peripherally-inserted IVs (PIVs) on the forearm or dorsal aspect of the hand.

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 physicians, or under the direction of a physician, who have been trained in the use of the ivWatch Model 400.

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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7 SPECIAL 510(K) SUMMARY

7.1 Administrative

Submitter Name	ivWatch, LLC
Applicant Address	469 McLaws Circle Williamsburg, VA 23185
Phone	855-489-2824
Fax	757-645-4760
Primary Contact	Jaclyn Lautz, Director of Regulatory Affairs and Quality Assurance
Primary Contact Email	jaclyn.lautz@ivwatch.com
Primary Contact Phone	855-489-2824 x7023
Date Prepared	January 12, 2016

7.2 Device

Trade Name	ivWatch Model 400
Manufacturer	ivWatch, LLC
510(k) Number	K153605
Device Class	II
Classification Name	Infusion Pump
Regulation Number	21 CFR 880.5725
Product Code	PMS (Peripheral Intravenous (PIV) Infiltration Monitor)

7.3 Predicate Device

Trade Name	ivWatch Model 400
Manufacturer	ivWatch, LLC
510(k) Number	K142374
Device Class	II
Classification Name	Infusion Pump
Regulation Number	21 CFR 880.5725
Product Code	MRZ (Accessories, Pump, Infusion)

7.4 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 on the forearm and dorsal aspect of the hand 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 signal are processed by proprietary ivWatch signal processing algorithms to determine if an infiltration event may have occurred. If changes in the optical properties of the tissue near the peripheral IV 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 peripheral IV site for a possible infiltration event.

7.5 Indications For Use

The indications for use are identical to the predicate device.

The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear, uncolored infusates, as an adjunctive device to the clinical evaluation in the hospital setting of patients 18 years old or greater with peripherally-inserted IVs (PIVs) on the forearm or dorsal aspect of the hand. 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 physicians, or under the direction of a physician, who have been trained in the use of the ivWatch Model 400.

7.6 Comparison of Modified Device with the Predicate Device

The subject device has the same technological characteristics and intended use as compared to the predicate device (K142374). The ivWatch Model 400 consists of the ivWatch patient monitor, a single-use sensor receptacle and a reusable optical sensor cable. There have been no changes to the ivWatch patient monitor and the single-use sensor receptacle of the subject device compared to the predicate device submission. The sensor cable of the subject device is the only component of the ivWatch Model 400 that has been modified. Specifically, the sensor cable sheathing, which is the outer protective layer encasing the flexible glass fibers, has been modified. The modification of the subject device's sheathing includes removing an additive and changing the colorant.

Item		Predicate Device – ivWatch Model 400 K142374	Subject Device – ivWatch Model 400 K153605
Monitor		ivWatch Patient Monitor	ivWatch Patient Monitor
Sterile, disposable patient-contacting component		ivWatch Sensor Receptacle	ivWatch Sensor Receptacle
Sensor Cable	Formulation	Pellethane 80AE Biosafe 2.7% Propell	Pellethane 80AE 2.7% Propell
	Colorant	Pantone 2975C	Pantone 646C
	Extrusion Method	Co-extrusion	Single extrusion

7.7 Performance Data

ivWatch has performed the following non-clinical/design verification testing based on the risk analysis conducted. The 510(k) submission included a summary of these design control activities to assure that the risks were adequately mitigated. The risks identified included biocompatibility and reprocessing. The mitigation for biocompatibility risks was to repeat the testing that was previously performed on the sensor cable sheathing of the predicate device per ISO 10993-1: Biological evaluation of medical devices, Part 1: Evaluation and testing. The reprocessing risks were mitigated by repeating the low-level disinfection validation and cleaning validation that was performed on the sensor cable of the predicate. The results of these tests demonstrate that the sensor cable modification of the ivWatch Model 400 is substantially equivalent to the sensor cable of the predicate device based on predetermined acceptance criteria. Clinical testing was not required for this submission.

Performance Characteristic		Acceptance Criteria	Result
Biocompatibility Testing *Performed on the sheathing of the sensor cable*	Sensitization	Per ISO 10993-10:2010, Non-sensitizer	Pass
	Irritation	Per ISO 10993-10:2010, Non-irritant	Pass
	Cytotoxicity	Per ISO 10993-5:2009, Non-toxic	Pass
Reprocessing Validation *Performed on the sensor*	Low Level Disinfection	Per AAMI TIR12 -2010, AAMI TIR30-2011 and Reprocessing Medical Devices in Health Care Settings: Validation	Pass
	Cleaning		Pass

cable		Methods and Labeling	

7.8 Conclusions

The risks associated with the modified ivWatch Model 400 have been identified and the design control activities demonstrate adequate risk mitigation. The modified ivWatch Model 400 is substantially equivalent to the predicate device.