DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2015

ivWatch, LLC
Javier Garriz
Vice President of Product Management
469 McLaws Circle
Williamsburg, VA 23185

Re: K142374
Trade/Device Name: ivWatch Model 400
Regulation Number: 21 CFR 880.5725
Regulation Name: Accessories, Pump, Infusion
Regulatory Class: Class II
Product Code: MRZ
Dated: January 16, 2015
Received: January 20, 2015

Dear Mr. Garriz:

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" (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 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,

Susan Runner DDS, MA

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
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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)*
K142374

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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5 510(K) SUMMARY

5.1 Administrative

Submitter Name	**ivWatch, LLC**
Applicant Address	469 McLaws Circle Williamsburg, VA 23185
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Fax	757-645-4760
Primary Contact	Javier Garriz, Vice President of Product Management
Primary Contact e-mail	javier.garriz@ivwatch.com
Primary Contact Phone	855-489-2824 x7016
Date Prepared	August 21, 2014

5.2 Device

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

5.3 Predicate Device

Trade Name	**Baxter SIGMA Spectrum Infusion Pump with Master Drug Library Model 35700**
Manufacturer	Baxter Healthcare Corporation
510(k) Number	K133801
Device Class	II
Classification Name	Infusion Pump
Regulation Number	21 CFR 880.5725
Product Code	FRN

5.4 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 ("Device") consists of the ivWatch Patient Monitor (IPM), a reusable optical sensor cable, and a single-use sensor receptacle.

The device uses visible and near-infrared light to measure changes in the optical properties of the tissue near a PIV insertion site; the measured changes are processed by proprietary ivWatch signal processing algorithms to determine if an infiltration event may have occurred. The device is indicated for use by medical professionals who are experienced with administering or monitoring peripheral IV therapy.

The IPM mounts to an IV pole, typically above the infusion pump. The sensor is secured in the receptacle and subsequently placed on the patient's skin near the peripheral IV insertion site for the duration of the IV monitoring. The fiber-optic sensor cable follows the IV line back to the pole-mounted IPM.

One end of the sensor cable attaches to the IPM; the other end snaps into the ivWatch sensor receptacle, which secures the sensor to the patient's skin. The sensor cable is a multiple-use disposable with a total useful life of approximately 240 hours of IV monitoring; it is intended to be cleaned between uses.

The ivWatch sensor receptacle is molded out of biocompatible plastics and includes biocompatible adhesives for attaching the receptacle to the patient's skin. The sensor receptacle is a single-use disposable and supplied sterile.

The IPM contains an optical system that generates light signals that are sent to the patient's skin (via the sensor cable) and measures the light returning from the patient's skin (also via the sensor cable). The Device uses low power LEDs as sources of visible and near-infrared (NIR) light. Optical fibers in the sensor cable deliver the light from the IPM to the sensor and transmit reflected light back to the IPM. The IPM also contains the hardware for executing the proprietary ivWatch signal processing algorithm.

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.

5.5 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, 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.

5.6 Comparison of Technological Characteristics with the Predicate Device

At a high level, the subject device (ivWatch Model 400) and the predicate device (Baxter SIGMA Spectrum with Master Drug Library Model 35700) have the same intended use – ensuring the delivery of IV fluids to the patient's vein. The predicate device includes technology to detect fault conditions (air-in-line, upstream and downstream occlusions) which may prevent the IV fluid from being delivered to the intended administration route(s). The subject device is intended for use in detecting one particular fault condition (IV infiltration) that prevents the IV fluid from being delivered to the intended intravenous administration route. In this sense, the subject device augments the type of faults detected by the predicate device (and indeed, any infusion pump) by detecting IV infiltration, consistent with the subject device's classification as an accessory to an infusion pump.

Both the subject and predicate devices monitor deviations in particular characteristics of the IV fluid which are correlative to possible faults in the delivery of the IV fluid to the intended intravenous administration route. The subject device monitors changes in the optical properties of the tissue surrounding the IV insertion site for signs of infusate accumulation in the subcutaneous space (i.e., IV infiltration); the predicate device uses pressure and ultrasonic waves to detect occlusion/blockage and air-in-line, respectively. However, this does not alter the intended use of the (accessory) subject and predicate devices--ensuring the delivery of IV fluids to the intended administration route (the patient's vein).

Both the subject and predicate devices issue visual and audible notifications when the measured values of the monitored characteristics exceed preset threshold values for those monitored characteristics (diffuse reflectance in the case of the subject device, pressure in the case of the predicate device).

5.6.1 Reference Device

To specifically address any safety concerns arising from the use of a red and infrared light source, a reference device was selected (Nellcor OxiMAX N-560 Pulse Oximeter, K021090). The safety of using infrared technology (within specified operating conditions) to determine human tissue properties has been well established by a variety of medical devices, most notably oximeters. The Nellcor OxiMAX N-560 Pulse Oximeter uses near-infrared (NIR) light within similar wavelengths as the ivWatch Model 400 to provide continuous monitoring of oxygenation levels and has been demonstrated as a safe and effective medical device.

Trade name	**OxiMAX N-560 Pulse Oximeter**
Manufacturer	Nellcor
510(k) Number	K021090
Device class	II
Classification name	Oximeter
Regulation Number	21 CFR 870.2700
Product Code	DQA

5.7 Performance Data

The following performance data were provided in support of substantial equivalence determination and to demonstrate safety and effectiveness.

5.7.1 Biocompatibility

The biocompatibility evaluation of the patient-contacting components of the ivWatch Model 400 device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

The following tests were performed:

- Sensitization
- Irritation
- Cytotoxicity

There are two skin-contacting components of the ivWatch Model 400: the ivWatch sensor receptacle and the ivWatch sensor cable. The ivWatch sensor receptacle complies with the biocompatibility requirements for prolonged duration contact (greater than 24 hours but less than 30 days) on intact skin. The

ivWatch sensor cable complies with the biocompatibility requirements for 24-hour contact on intact skin.

5.7.2 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the ivWatch Model 400, consisting of the ivWatch Patient Monitor and sensor cable. The system conforms and meets the requirements of IEC 60601-1-2: 3rd Ed. 2007. ivWatch Model 400 was also tested and determined to be compliant to 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).

5.7.3 Software Verification and Validation Testing

Software verification and validation testing for the ivWatch Model 400 were conducted and documented in accordance with the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Software validation is compliant to IEC 60601-1 3rd edition – Amendment 1, and therefore IEC 62304.

The software code on the IPM was segregated into two types:

1. Software whose function is consistent with the "moderate level of concern" classification, as stated in the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May, 2005). As stated in the guidance document, failures or latent design flaws in software having the "moderate" level of concern may result in minor to moderate injury to the patient, or it may indirectly affect the patient in that incorrect or delayed information could result in injury to the patient.

2. Software which presents a "minor level of concern."

The device is intended as a supplement (aid) to, and not a replacement for regular clinician assessment of the PIV site (i.e., regular clinician assessment is still in effect). Accordingly, only the modules that involved setting the level and duration of the emitted light were treated as having "moderate" level of concern, since the only software-controlled output that contacts the patient in any way is the light emitted by the LEDs.

5.7.4 Bench Testing

Computer simulations were used to identify the optimal design for the ivWatch sensor. Simulation results were validated in bench tests using an *ex vivo* porcine foot model. Optical safety testing was performed and indicated that the optical radiation emitted by the ivWatch device is significantly less than the limits set forth by industry standards (ANSI Z136.1 – 2007).

5.7.5 Clinical Studies

A series of six IRB-approved verification and validation clinical studies were performed for the development and validation of the ivWatch Model 400. Verification studies investigated the specific effect of infiltration characteristics or patient attributes on the performance of the ivWatch Model 400 device. The validation studies assessed the performance (e.g., sensitivity, false notification rate) of the ivWatch Model 400 device. The results demonstrated that the ivWatch Model 400 could assist clinicians in identifying the early stages of a PIV infiltration. There were no adverse events during the clinical studies.

5.7.6 Summary

The results of the performance testing indicate that the ivWatch Model 400 is substantially equivalent to the Baxter SIGMA Spectrum Infusion Pump with MDL and raises no concerns about safety or efficacy of the device.

5.8 Conclusions

The ivWatch Model 400 is found to be substantially equivalent to the predicate device, as both have the same intended use and mechanism of action. Any safety concerns arising from the use of a red and infrared light source are addressed using a reference device. Any differences between the ivWatch Model 400 and the predicate were addressed through performance testing and such differences were determined to have no effect on the safety or efficacy of the device.