August 24, 2022

ivWatch, LLC
Holly Novak
Vice President, Regulatory Affairs & Quality Assurance
700 Tech Center Parkway, Suite 300
Newport News, Virginia 23606

Re: K222212
Trade/Device Name: ivWatch Model 400
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PMS
Dated: July 22, 2022
Received: July 25, 2022

Dear Holly Novak:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Payal Patel
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222212

Device Name

ivWatch Model 400 (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 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.

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

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K222212 - 510(K) SUMMARY

Administrative

Submitter Name	**ivWatch®, LLC**
Applicant Address	700 Tech Center Parkway, Suite 300 Newport News, VA 23606
Establishment Registration	3011490091
Phone	855-489-2824
Fax	757-224-5009
Primary Contact	Holly Novak, Vice President of Regulatory Affairs and Quality Assurance
Primary Contact Email	holly.novak@ivwatch.com
Primary Contact Phone	855-489-2824 x7046
Date	August 23, 2022

Subject Device

Trade Name	ivWatch® Model 400
Manufacturer	ivWatch®, LLC
510(k) Number	K222212
Device Class	II
Regulation Number	21 CFR 880.5725
Regulation Name	Infusion pump
Product Code	PMS
Common Name	Peripheral Intravenous (PIV) Infiltration Monitor

Predicate 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
Common Name	Peripheral Intravenous (PIV) Infiltration Monitor

Device Description

The predicate device (K162478), the ivWatch® Model 400, consists of the ivWatch Patient Monitor, a reusable Fiber Optic Sensor Cable, and a single-use Sensor Receptacle. The subject device includes the transfer of the EO sterilization from the Category A chamber method to a Category B flexible bag method. This Category B flexible bag method was the same performed under ivWatch's most recent 510K (K192385).

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 signal are processed by 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.

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 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.

The indications for use of the subject device are the same as the predicate (K162478).

Comparison of the Subject Device to the Predicate Devices

The subject device is a modification to the legally marketed ivWatch® Model 400. The subject device was EO sterilized using a Category B flexible bag method. The subject and predicate devices have the same technological characteristics, design, intended use and indications for use.

Criteria	Associated Standard	Predicate Device Results/Comments	Subject Device Results/Comments	Substantial Equivalence Discussion
Sterilization	ISO 14937 ISO 10993-7	Pass Sterilization SAL and EO residual limits	Pass Sterilization SAL and EO residual limits	Equivalent

Parameter	Sensor Receptacle (Predicate K162478)	Sensor Receptacle (Subject)
Sterilization Method	EO half-cycle overkill approach	EO half-cycle overkill approach
Incubation time	7 days	7 days
Minimum SAL of 10^{-6}	$<10^{-6}$	$<10^{-6}$
EO Residual (Limit: < 4 mg)	Pass	Pass
ECH Residual (Limit: < 9 mg)	Pass	Pass
Testing	Device met acceptance criteria to: Sterilization ISO 11135-1:2007 EO Residuals ISO 10993-7:2008	Device met acceptance criteria to: Sterilization ISO 14937:2009 and AAMI TIR56:2013 EO Residuals ISO 10993-7:2008

Summary Table

Item	Predicate Device K162478	Subject Device	Substantial Equivalence Discussion
Trade Name	ivWatch Model 400	ivWatch Model 400	Equivalent
Manufacturer	ivWatch, LLC	ivWatch, LLC	Equivalent
510(k) Number	K162478	K222212	N/A
Product Code	PMS	PMS	Equivalent
Device Class	II	II	Equivalent
Type of Use	Prescription Use (RX)	Prescription Use (RX)	Equivalent
Classification Name	Peripheral Intravenous (PIV) Infiltration Monitor	Peripheral Intravenous (PIV) Infiltration Monitor	Equivalent
Regulation Number	21 CFR 880.5725	21 CFR 880.5725	Equivalent
Intended Use	The ivWatch Model 400 is intended to aid in the detection of infiltrations and extravasations during peripheral IV infusion therapy in pediatric and adult patients. The user profile is healthcare practitioners who are experienced in IV administration and management and located at hospitals and similar medical care facilities.	The ivWatch Model 400 is intended to aid in the detection of infiltrations and extravasations during peripheral IV infusion therapy in pediatric and adult patients. The user profile is healthcare practitioners who are experienced in IV administration and management and located at hospitals and similar medical care facilities.	Equivalent
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 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).	Equivalent

Item	Predicate Device K162478	Subject Device	Substantial Equivalence Discussion
	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.	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.	
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, which may indicate that fluid is not being delivered to the intended intravenous administration route (i.e., if an infiltration or extravasation has occurred).	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, which may indicate that fluid is not being delivered to the intended intravenous administration route (i.e., if an infiltration or extravasation has occurred).	Equivalent
Mechanism of Action	Device is turned on; sensor is placed near the IV insertion site; a baseline is established and characteristics of the tissue around the IV site are monitored for deviations beyond preset threshold values.	Device is turned on; sensor is placed near the IV insertion site; a baseline is established and characteristics of the tissue around the IV site are monitored for deviations beyond preset threshold values.	Equivalent
System Components	ivWatch Patient Monitor, Sensor Receptacle, and Optical Sensor Cable.	ivWatch Patient Monitor, Sensor Receptacle, and Optical Sensor Cable.	Equivalent

Item	Predicate Device K162478	Subject Device	Substantial Equivalence Discussion
Sterilization Method	Category A, EO Chamber method	Category B, Flexible Bag method	Although the method of EO sterilization differs between the subject and predicate devices, the subject device was tested to confirm a minimum SAL of 10-6 in compliance with ISO 14937:2009 using the overkill method. EO/ECH residuals were also tested and passed the allowable limits per ISO 10993-7:2008. Test results verify the sterilization methods of the predicate and subject device are equivalent.

Conclusions

The technological characteristics, principles of operation and intended use of the ivWatch® Model 400 subject device and the predicate device are the same. Test results show that the ivWatch® Model 400 subject device meets all pre-defined acceptance criteria. The ivWatch® Model 400 subject device performs as intended, does not pose any additional risk to patient safety, and is substantially equivalent to the legally marketed predicate device (K162478).