March 15, 2024

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

Re: K233881
Trade/Device Name: ivWatch® Model 400
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: PMS
Dated: February 16, 2024
Received: February 16, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

David Wolloscheck, Ph.D.
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

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.

510(k) Number *(if known)*
K233881

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 and iron sucrose 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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K233881 - 510(K) SUMMARY

Device Submitter	**ivWatch, LLC** 700 Tech Center Parkway, Suite 300 Newport News, VA 23606
Contact Person	Holly Novak, Vice President of Regulatory Affairs and Quality Assurance holly.novak@ivwatch.com 855-489-2824 x7046 Fax: 757-224-5009
Date Prepared	December 07, 2023

Subject Device

Trade Name	ivWatch® Model 400
Device Class	II
Regulation Number	21 CFR 880.5725
Product Code	PMS
Common Name	Peripheral Intravenous (PIV) Infiltration Monitor
Classification Name	Infusion pump

Predicate Device

Trade Name	ivWatch® Model 400
510(k) Number	K192385
Device Class	II
Regulation Number	21 CFR 880.5725
Product Code	PMS
Common Name	Peripheral Intravenous (PIV) Infiltration Monitor
Classification Name	Infusion pump

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 predicate device includes a Patient Monitor, a Fiber Optic Sensor Cable, and a disposable Sensor Receptacle. Under K192385 the system was expanded to add three Device Accessories including an Extension Module, a Patient Cable and SmartTouch Sensor. The Device Accessories expand system's functionality to support two sensor technologies (fiber optic and electronic).

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 uses visible and near-infrared light to measure changes in the optical properties of the tissue near a PIV insertion site. The ivWatch Patient Monitor (IPM) contains an optical system that generates visible and near-infrared light signals that are sent through the sensor cable to the patient's skin. Simultaneously, the IPM measures the light reflected back through the 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.

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 intended use of the subject device is the same as the predicate (K192385).

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 and iron sucrose 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 (K192385), with the addition of iron sucrose as an indicated infusate.

Comparison of the Subject Device to the Predicate Devices

The subject device includes all the same devices and device accessories as the predicate. Under this 510K submission, the only change is to the Indications for use to add iron sucrose as an indicated infusate. There are no changes to the devices.

Summary Table

Item	Predicate Device K192385	Subject Device	Substantial Equivalence Discussion
Trade Name	ivWatch Model 400	Same	Equivalent
Manufacturer	ivWatch, LLC	Same	Equivalent
510(k) Number	K192385	K233881	N/A
Product Code	PMS	Same	Equivalent
Device Class	II	Same	Equivalent
Common Name	Peripheral Intravenous (PIV) Infiltration Monitor	Same	Equivalent
Regulation Number	21 CFR 880.5725	Same	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.	Same	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	The ivWatch Model 400 is indicated for the detection of subcutaneous infiltrations and extravasations of 10 cc or less of optically clear and iron sucrose infusates, as an adjunctive device to the	Equivalent Bench testing results support device detection of iron

Item	Predicate Device K192385	Subject Device	Substantial Equivalence Discussion
	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.	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.	sucrose; iron infusates do not impact device safety or effectiveness.
Sterilization	The SmartTouch Sensor and Sensor Receptacles are sterilized using the EO half-cycle overkill approach. A minimum SAL of 10^{-6} per ISO 11135, EO residuals of < 4mg and ECH residuals of < 9mg were achieved.	Same	Equivalent
Shelf-Life	Packaging passed Burst Testing per ASTM F1140, and Bubble Emission Leak Test per ASTM F2096. Sensor Receptacle 2 years SmartTouch Sensor 1 year	Packaging passed Burst Testing per ASTM F1140, and Bubble Emission Leak Test per ASTM F2096. Sensor Receptacle 3 years SmartTouch Sensor 3 years	Equivalent Shelf life was determined by meeting acceptance criteria in compliance with requirements outlined in ASTM F1886, ASTM F2096, and ASTM F1140.

Item	Predicate Device K192385	Subject Device	Substantial Equivalence Discussion
Reprocessing	The Patient Monitor, Extension Module, Fiber Optic Sensor Cable and Patient Cables are to be cleaned/disinfected in between uses. Cleaning and low-level disinfection validation testing passed all pre-defined acceptance criteria in compliance with AAMI TIR12 and AAMI TIR30.	Same	Equivalent
Biocompatibility	The Sensor Receptacle, Fiber Optic Sensor Cable, SmartTouch Sensor and Patient Cable are classified as having prolonged duration (greater than 24 hours but less than 30 days) patient-contacting components. Biocompatibility testing was conducted in compliance with ISO 10993-1, 10993-5, 10993-10. Results show that the patient-contacting components pass all pre-defined acceptance criteria defined for cytotoxicity, sensitization, and irritation testing.	Same	Equivalent
Electromagnetic Compatibility (EMC) and Electrical Safety	EMC and electrical safety testing were conducted on the and results show that the ivWatch® Model 400 with Device Accessories complies with the requirements of EN / IEC 60601-1-2 4th Edition and IEC 60601-1 3rd Edition.	Same	Equivalent

Item	Predicate Device K192385	Subject Device	Substantial Equivalence Discussion
Software Verification and Validation Testing	Software verification and validation testing for the ivWatch® Model 400 with Device Accessories were conducted and documentation was provided in accordance FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and IEC 62304.	Same	Equivalent
Performance Testing	Optical safety testing was performed and indicated that the optical radiation emitted by the sensors significantly less than the limits defined in ANSI Z136.1.	Same	Equivalent
	A series of IRB-approved clinical studies were performed for the verification and validation of the ivWatch Model 400 with Device Accessories. All submitted clinical studies were conducted in the United States and in compliance with 21 CRF 50, 21 CFR 54, 21 CRF 56 and 21 CRF 812, ICH E6 and ISO 14155. The results demonstrated that the ivWatch Model 400 with Device Accessories meets the devices intended use and raises no concerns regarding safety and efficacy.	Same	Equivalent

Item	Predicate Device K192385	Subject Device	Substantial Equivalence Discussion
	N/A, Iron data and claims were not included in predicate submission.	Data supports the update to the ivWatch Patient Monitoring System's Indications for Use to detect iron sucrose infusions in addition to optically clear infusions. Iron concentrations from 1mg/ml to 20mg/ml were tested. Results showed: • Mean signal drops Saline: 23.7% (std: 6.79%) Iron: 47.1% (std: 7.97%) • Iron injection signals not weaker than saline signals (p≈1.000) • Diluted iron signal (1mg/ml) is stronger signal than saline. • Signal strength increases with higher concentration of iron.	Equivalent Bench testing results support device detection of iron sucrose; iron infusates do not impact device safety or effectiveness.

Conclusions

The technological characteristics, principles of operation and intended use of the ivWatch® Model 400 subject device and the predicate device are similar. Test results show that the ivWatch® Model 400 subject device meets all pre-defined acceptance criteria. The nonclinical and clinical tests demonstrate that the ivWatch® Model 400 is substantially equivalent to the predicate device, K192385.