July 2, 2020

ivWatch, LLC
Holly Novak
Director Regulatory Affairs and Quality Assurance
630 Hofstadter Road, Suite 300
Newport News, Virginia 23606

Re: K192385
Trade/Device Name: ivWatch Model 400, Device Accessories: Extension Module, SmartTouch Sensor, Patient Cable
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: PMS
Dated: May 29, 2020
Received: June 1, 2020

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,

Sapana Patel -S

for Tina Kiang, Ph.D.
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

510(K) SUMMARY

7.1 Submitter

Submitter Name	**ivWatch, LLC**
Submitter Address	630 Hofstadter Road, Suite 300 Newport News, VA 23606
Establishment Registration	3011490091
Phone	855-489-2824
Fax	757-224-5009
Primary Contact	Holly Novak, Vice President, Regulatory Affairs and Quality Assurance
Primary Contact Email	holly.novak@ivwatch.com
Primary Contact Phone	855-489-2824 x7046
Date Prepared	June 18, 2020

7.2 Subject Device

Trade Name	ivWatch® Model 400 Device Accessories: Extension Module, Patient Cable and SmartTouch™ Sensor
Manufacturer	ivWatch, LLC
510(k) Number	K192385
Device Class	II
Regulation Number	21 CFR 880.5725
Product Code	PMS
Device Classification	Peripheral Intravenous (PIV) Infiltration Monitor

7.3 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
Device Classification	Peripheral Intravenous (PIV) Infiltration Monitor

7.4 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 sterile Sensor Receptacle. The subject device includes the addition of Device Accessories to the ivWatch® Model 400 including an Extension Module, reusable Patient Cable and a single-use electronic SmartTouch™ Sensor. The Device Accessories expand the current ivWatch® Model 400 architecture to support the reusable Fiber Optic Sensor (predicate device) and an electronic single-use sterile SmartTouch™ Sensor (subject device). Both the predicate and subject device provide 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 with Device Accessories uses visible and near-infrared light to measure changes in the optical properties of the tissue near a PIV insertion site. Light signals generated by the SmartTouch™ Sensor are sent to the patient's tissue near an PIV site. Changes to the light signals are received by the SmartTouch™ Sensor and electrical signals are transferred through the Patient Cable to the Extension Module where embedded software analyzes the data to determine whether conditions indicate that an infiltration event may have occurred. The information is then sent from the Extension Module to the ivWatch® Patient Monitor for display. If changes in the diffuse reflectance in the tissue near the PIV site are consistent with an infusate pooling in the subcutaneous tissue, the ivWatch® Patient Monitor emits audible and visual notifications intended to prompt the clinician to inspect the peripheral IV site for a possible infiltration event.

7.5 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 (K162478).

7.6 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 is the same as the predicate (K162478).

7.7 Comparison of the Subject Device to the Predicate Devices

The subject device (ivWatch® Model 400 Device Accessories) is a modification to the legally marketed ivWatch® Model 400. The subject device expands the functionality of the ivWatch® Model 400 (predicate) with the addition of three device accessories: Extension Module, Patient Cable and SmartTouch™ Sensor. The subject and predicate devices have the same technological characteristics, intended use and indications for use.

The subject and predicate devices share the same technological elements:

- Sensor is placed near the IV insertion site to emit optical signals and detect changes in the diffuse reflectance of the tissue.
- The optical signals emitted and detected by the sensor are visible and nearinfrared light signals.
- The optical signal received by the sensor is altered if the IV fluid accumulates in the tissue surrounding the intended intravenous administration route underneath the sensor.
- The reflected optical signal from the tissue is sent back to the device for analysis by ivWatch's algorithm to determine if an infiltration may have occurred.
- Software in the Patient Monitor controls the user interface including the issuance of audible and visual notifications for a possible infiltration event.

The following technical differences exist between the subject and predicate devices:

- The subject device has the optical components at the SmartTouch™ Sensor head while the predicate device has the optical components in the Patient Monitor.
- Light is generated and detected in the subject device SmartTouch™ Sensor head while the predicate device light generation and detection is at the Patient Monitor.
- Electrical signals are transmitted to and from the SmartTouch™ Sensor head through the Patient Cable to the Extension Module for signal processing. The predicate device light signals are transmitted through the Fiber Optic Sensor Cable to the patient's skin and simultaneously reflected light signal from the patient's skin are transmitted back to the Patient Monitor for data analysis.
- The patient contacting SmartTouch™ Sensor (subject) is dimensionally smaller than the Sensor Receptacle (predicate).
- The predicate device uses fiber optics to transmit the signal, while the subject devices uses an electronic signal.

7.8 Performance Data

The subject device underwent the exact same performance testing as the predicate device in support of substantial equivalence. A summary of the completed testing is provided below.

7.8.1 Sterilization and Shelf Life

The SmartTouch™ Sensor is sterilized by ethylene oxide (EO)) per ISO 14937-1:2009 and AAMI TIR56:2013 (R2016). EO and ethylene chlorohydrin residuals are in compliance with ISO 10993-7:2008. In addition, the SmartTouch™ Sensor passed package testing in compliance with ISO 11607-1:2006/A1:2014, ASTM F1140/F1140M-13, ASTM F2096-11 and ASTM D4169-16.

The Patient Cable is designed to be cleaned and disinfected between uses. Cleaning and low-level disinfection validation testing passed all pre-defined acceptance criteria in compliance with AAMI TIR12-2010 and AAMI TIR30-2011.

7.8.2 Biocompatibility

The 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 10993-1:2018, 10993-5:2009, 10993-10:2010. Results show that the patient contacting components of the SmartTouch™ Sensor and Patient Cable pass all

pre-defined acceptance criteria defined for cytotoxicity, sensitization and irritation testing.

7.8.3 Electromagnetic Compatibility (EMC) and Electrical Safety

EMC and electrical safety testing were conducted on the Extension Module (subject device) while connected to the Patient Monitor (predicate device) 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.

7.8.4 Software Verification and Validation Testing

Software verification and validation testing were conducted on the Extension Module (subject device) while connected to the Patient Monitor (predicate device) for the ivWatch® Model 400 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.

Cybersecurity was provided in accordance of "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" Guidance document.

7.8.5 Performance Testing

7.8.5.1 Bench Testing

Optical safety testing was performed on the subject device and indicated that the optical radiation emitted by the SmartTouch™ Sensor is significantly less than the limits defined in ANSI Z136.1 (2014).

7.8.5.2 Clinical Studies

A series of series of five verification and two validation IRB-approved clinical studies were performed for the development and validation of the modified ivWatch® Model 400 with Device Accessories.

The device validation for non-infiltrated tissue study showed a false notification was recorded once every 6.29 days, on average (6 false red notifications in 922 hours) and a false yellow notification was issued once every 4.78 days, on average (8 false yellow notifications in 922 hours).

In the Device Validation for Infiltrated Tissue study, the SmartTouch issued red and yellow notifications for 99.0% (97/98, 95% confidence interval: 94.5% to 100.0%) of early stage infiltrations. The infiltration rate was selected from a range extending from 5 mL/hr to 150 mL/hr. An analysis of the detected volume indicated the SmartTouch sensor issued red and yellow notifications at an average of 2.13 mL and 2.02 mL of infiltrated saline, respectively.

There were no new safety issues identified and no adverse events during any of the verification and validation clinical studies.

7.8.6 Summary

The results of the performance testing indicate that the ivWatch® Model 400 with Device Accessories is substantially equivalent to the predicate device (K162478) and raises no concerns regarding safety and effectiveness.

7.9 Summary Table

Item	Predicate Device K162478	Subject Device K192385	Substantial Equivalence Discussion
Trade Name	ivWatch Model 400	ivWatch Model 400 Device Accessories	**N/A**
Manufacturer	ivWatch, LLC	ivWatch, LLC	**Equivalent**
510(k) Number	K162478	K192385	**N/A**
Product Code	PMS	PMS	**Equivalent**
Device Class	II	II	**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**

Item	Predicate Device K162478	Subject Device K192385	Substantial Equivalence Discussion
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.	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.	**Equivalent**

Criteria	Associated Standard	Predicate Device Results/Comments	Subject Device Results/Comments	Substantial Equivalence Discussion
Basic Safety	EN/IEC 60601-1	Pass Device has no essential performance	Pass Device has no essential performance	**Equivalent**
EMC	EN/IEC 60601-1-2	Pass Class A Group 1	Pass Class A Group 1	**Equivalent**

Criteria	Associated Standard	Predicate Device Results/Comments	Subject Device Results/Comments	Substantial Equivalence Discussion
Packaging/Shipping	ASTM D1469	Compliant to ASTM Standard Assurance Level 1	Compliant to ASTM Standard Assurance Level 1	**Equivalent**
Aging	ISO 11607-1 ASTM F1140 ASTM F2096	Pass	Pass	**Equivalent**
Biocompatibility	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization and Irritation	Pass Devices are non-toxic, non-sensitizer, and non-irritant	Pass Devices are non-toxic, non-sensitizer, and non-irritant	**Equivalent**
Sterilization	ISO 11135 ISO 10993-7	Pass Sterilization SAL and EO residual limits	Pass Sterilization SAL and EO residual limits	**Equivalent**
Low Level Disinfection and Cleanability	AAMI TIR12 AAMI TIR30	Pass Six (6) log reduction in microbial levels, pass protein and hemoglobin residuals	Pass Six (6) log reduction in microbial levels, pass protein and hemoglobin residuals	**Equivalent**
Usability	FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices	Device found to be safe and effective for the intended users, uses, and use environments	Device found to be safe and effective for the intended users, uses, and use environments	**Equivalent**

Criteria	Associated Standard	Predicate Device Results/Comments	Subject Device Results/Comments	Substantial Equivalence Discussion
Software	IEC 62304	Software design, development and validation is compliant to IEC 62304	Software design, development and validation is compliant to IEC 62304	**Equivalent**

7.10 Conclusions

The technological characteristics, principles of operation and intended use of the ivWatch® Model 400 with Device Accessories and the predicate device are the same. Differences between the subject and predicate devices were addressed through verification, validation and performance testing. Test results show that the ivWatch® Model 400 with Device Accessories meets all pre-defined acceptance criteria. The ivWatch® Model 400 with Device Accessories performs as intended, does not pose a risk to patient safety, and is substantially equivalent to the legally marketed predicate device.