January 23, 2021

Edan Instruments, Inc.
Alice Yang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District Pingshan District
Shenzhen, Guangdong 518122
China

Re: K202336
Trade/Device Name: Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, DPS, DSI, MLD, DRT, DXN, DSK, FLL, DQA, BZQ, CCK, CBS, CBR, CCL, CBQ, NHO, NHQ, NHP
Dated: December 25, 2020
Received: December 28, 2020

Dear Alice Yang:

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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(K) Summary

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. **Submitter:** Edan Instruments, Inc.
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Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

Contact person: Alice Yang
Preparing date: August 11, 2020

2. Device name and classification:

Trade Name: Patient Monitor, Model: iM50, iM60, iM70, iM80
Common/Usual Name: Patient Monitor

Classification Name	**Product code**
21 CFR 870.1025 Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)	MHX
Subsequent Product Code	
21 CFR 868.2375 Electrocardiograph	DPS
21 CFR 870.2340 Detector and Alarm, Arrhythmia	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	MLD
21 CFR 870.2300 Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	DRT
21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive	DXN
21 CFR 870.1110 Computer, Blood-Pressure	DSK
21 CFR 880.2910 Thermometer, Electronic, Clinical	FLL
21 CFR 870.2700 Oximeter	DQA
21 CFR 868.2375	BZQ

Monitor, Breathing Frequency	
21 CFR 870.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	CCK
21 CFR 868.1620 Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Conc.)	CBS
21 CFR 868.1700 Analyzer, Gas, Nitrous-Oxide, Gaseous Phase (Anesthetic Conc.)	CBR
21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase	CCL
21 CFR 868.1500 Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)	CBQ
21 CFR 868.1500 Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)	NHO
21 CFR 868.1500 Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)	NHQ
21 CFR 868.1500 Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)	NHP

Regulatory Class: Class II

3. **Predicate Device(s):**

1) Edan Instruments, Inc, Patient Monitor Model X8,X10,X12, K192514 (Primary)

2) Edan Instruments, Inc, Patient Monitor Model elite V5, elite V6, elite V8, K160981 (Reference)

3) Shenzhen Mindray Bio-Medical Electronics Co., LTD. BeneVision N Series Patient Monitors, K182075 (Reference)

4) Philips Medizin Systeme Boeblingen GmbH， Patient Monitor Mx700，

K182979 (Reference)

4. **Device Description:** The iM series Patient Monitor including iM50, iM60, iM70 and iM80 can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormalities so that doctors and nurses can respond to the patient's situation as appropriate.

5. **Indication for Use** The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), and Anaesthesia gas(AG).

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are not intended for MRI environments.

6. Predicate Device Comparison

The table below compares the indication for use and key technological feature of the subject devices to the predicate device (Patient Monitor Model X8, X10, X12, K160981).

Item	**<Subject Device> (iM50,iM60,iM70,iM80)**	**<Predicate Device> (X8,X10,X12)**	**Comparison Result**
Manufacturer/K#	Current Submission	K192514	——
Intended Use			
Description	The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters	The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in	Different. The AG indication is not present in the primary predicate, but is present in Edan Patient Monitor V series

	include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), and **Anaesthesia gas(AG).** The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are not intended for MRI environments.	hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.). The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are not intended for MRI environments.	K160981
ECG module			
Lead Mode	3 Electrodes; 5 Electrodes; 6 Electrodes; 10 Electrodes	3 Electrodes; 5 Electrodes; 6 Electrodes; 10 Electrodes	Same
Arrhythmia analyses	ASYSTOLE, VFIB/VTAC, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP	ASYSTOLE, VFIB/VTAC, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP	Same
ST value			
Measurement Range	-2.0 mV to +2.0 mV	-2.0 mV to +2.0 mV	Same
Pace			
Pulse Indicator	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 µs to 100 µs	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 µs to 100 µs	Same
PVC			
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min	Same
HR			
Measurement range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm	Same
QT Analysis			

QT/QTc/ΔQTc measurement	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms Δ QTc Range: -600 ms ~ 600 ms	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms Δ QTc Range: -600 ms ~ 600 ms	Same
RESP module			
Principle of Operation	Impedance between RA-LL, RA-LA	Impedance between RA-LL, RA-LA	Same
Measurement Range	Adult: 0 to 120 rpm Pediatric/neonate: 0 to 150 rpm	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	Same
NIBP module (EDAN)			
Technique	Oscillometry	Oscillometry	Same
Measurement Range	Measurement range: Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 Mean 15-260 15-215 15-125	Measurement range: Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 Mean 15-260 15-215 15-125	Same
PR from NIBP			
Measurement range	40 bpm to 240 bpm	40 to 240 bpm	Same
Omron and Suntech NIBP module is the same as K160981			
SpO2 module(EDAN)			
Measurement Range	SpO2 0% to 100% Pulse Rate 25 to 300 bpm	SpO2 0% to 100% Pulse Rate 25 to 300 bpm	Same
Nellcor SpO2 module is the same as K160981			
Temperature module			
Number of channels	2	2	Same
Measurement Range	0 °C to 50 °C(32 ºF to 122 ºF)	0 °C to 50 °C(32 ºF to 122 ºF)	Same
IBP module			
Measurement Range	PA/PAWP: (-6 to +120) mmHg CVP/RAP/LAP/ICP: (-10 to +40) mmHg P1/P2: (-50 to +300) mmHg	PA/PAWP: (-6 to +120) mmHg CVP/RAP/LAP/ICP: (-10 to +40) mmHg P1/P2: (-50 to +300) mmHg	Same

C.O. Module			
Technique	Thermodilution Technique	Thermodilution Technique	Same
Measurement range	C.O.: 0.1 to 20L/min TB: 23 ℃to 43 ℃(73.4 ℉to 109.4 ℉) TI: -1 ℃to 27 ℃(30.2 ℉to 80.6 ℉)	C.O.: 0.1 to 20L/min TB: 23° C to 43 °C(73.4 °F to 109.4 °F) TI: -1 °C to 27 °C(30.2 °F to 80.6 °F)	Same
CO2 Module			
Intended Patient	Adult, pediatric, neonatal	Adult, pediatric, neonatal	Same
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR	$EtCO_2$, $FiCO_2$, AwRR	Same
Measuring Range	CO2:0 mmHg to 150 mmHg (0 % to 20%) AwRR: 2 rpm to 150 rpm	CO2:0 mmHg to 150 mmHg (0 % to 20%) AwRR: 2 rpm to 150 rpm	Same
Respironics and Masimo CO2 module are the same as K160981			
AG module (EDAN G7 module)			
Measure Parameters	CO_2、N_2O、O_2、HAL、ISO、ENF、SEV、DES、AwRR、MAC	\	Edan G7 module is similar to Dräger AG module cleared by K160981
Measuring Range	**CO_2: 0%～15Vol %** N_2O: 0%～100 Vol % **HAL/ISO: 0%-8Vol %** **ENF: 0%-8 Vol %** SEV: 0%-10 Vol % DES: 0%-20 Vol % O_2: 0%～100 Vol % **AwRR: 2rpm-100rpm**		
Masimo and **Dräger** AG module are the same as K160981			
WI-FI			
IEEE	802.11a/b/g/n	802.11a/b/g/n	Same
Frequency Band	2.4 GHz ISM band & 5 G ISM band	2.4 GHz ISM band & 5 G ISM band	Same
Power supply			
AC power			
Requirement	100-240V, 50/60Hz	100-240V, 50/60 Hz	Same
Battery			
Rechargeable Battery	Yes	Yes	Same

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

iM Series Patient Monitors were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.
- AIM Standard 7351731 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

Performance testing-Bench

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- IEC 60601-1-8:2006 + Am1:2012 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30:2009+A1:2013 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- IEC 60601-2-49:2011 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2018 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2017+A1:2018 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

- ISO 80601-2-61: 2017 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEEE ANSI C63.27:2017 American National Standard for Evaluation of Wireless Coexistence

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Clinical data: Not applicable.

Summary

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate device.

8. Conclusion

The bench testing data and software verification and validation demonstrate that iM series Patient Monitor are substantially equivalent to the predicate device.