March 8, 2024

Edan Instruments, Inc.
Tracy Yue
Regulatory Affairs Engineer
15 Jinhui Road, Jinsha Community, Kengzi Sub-district
Pingshan District, Shenzhen, Shenzhen 518122
China

Re: K233038
Trade/Device Name: Vital Signs monitor, Model: iM3s, iM3As, iM3Bs, iHM3s
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: September 25, 2023
Received: September 25, 2023

Dear Tracy Yue:

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,

Stephen C. Browning -S

LCDR Stephen Browning
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

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)*
K233038

Device Name
Vital Signs monitor, Model: iM3s, iM3As, iM3Bs, iHM3s

Indications for Use *(Describe)*
The device is intended to be used for measuring, storing, and reviewing of, and to generate prompts for, multiple physiological parameters of adults and pediatrics (including neonates). The device is intended for use by trained healthcare professionals in hospital environments.
Parameters include: NIBP, SpO2, PR (pulse rate), TEMP.
The F3000 Quick Temp module is not intended for neonates.
The device is not intended for MRI environments.

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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510(K) Summary

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

1. Submitter:

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

Contact person: Tracy Yue

Preparing date: September 25, 2023

2. Device name and classification:

Trade Name: Vital Signs Monitor, Model: iM3s, iM3As, iM3Bs, iHM3s

Common/Usual Name: Vital Signs Monitor

Classification Name	**Product code**
21 CFR 870.2300 Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	MWI
Subsequent Product Code	
21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive	DXN
21 CFR 880.2910 Thermometer, Electronic, Clinical	FLL
21 CFR 870.2700 Oximeter	DQA

Regulatory Class: Class II

3. Predicate Device(s):

1) Edan Instruments, Inc., Vital Signs Monitor:iM3s, iM3As, iM3Bs, iHM3s, K202892 (Primary predicate device)
2) Shenzhen Mindray Bio-Meidcal Electronics Co., LTD, VS 9 Vital Signs Monitor, K221267 (Reference device)
3) HeTaiDa Technology Co., Ltd, Non-contact Infrared Body Thermometer, Model HTD8808C, K203332 (Reference device)
4) TaiDoc Technology Corporation, FORA IR20B EAR

THERMOMETER , K090395 (Reference device)

4. Device Description: The iM3s series vital signs monitors including iM3s\iM3As\iM3Bs\ iHM3s are intended to be used for measuring, storing, reviewing of, and generating prompts for multiple physiological parameters of adults and pediatrics.

5. Indication for Use The device is intended to be used for measuring, storing, and reviewing of, and to generate prompts for, multiple physiological parameters of adults and pediatrics (including neonates). The device is intended for use by trained healthcare professionals in hospital environments.

Parameters include: NIBP, SpO2, PR (pulse rate), TEMP.

The F3000 Quick TEMP module is not intended for neonates.

The device is not intended for MRI environments.

6. Predicate Device Comparison

The intended use of the subject devices iM3s series is the same as the primary predicate device Vital Signs Monitor: iM3s, iM3As, iM3Bs, iHM3s (K202892) which is intended to be used for measuring, storing, and reviewing of, and to generate prompts for, multiple physiological parameters of adults and pediatrics in healthcare environments by trained healthcare professionals.

The table below compares the indication for use and parameter modules of the subject devices to the primary predicate devices.

Manufacturer/Item	<***Predicate Device***> EDAN Instrument Inc. iM3s series Vital Signs Monitor	<***Subject Device***> EDAN Instrument Inc. iM3s series Vital Signs Monitor	**Comparison Result**
K#	K202892	Current Submission	——
Intended Use			
Description	The device is intended to be used for measuring, storing, and reviewing of, and to generate prompts for, multiple physiological parameters of adults and pediatrics. The device is intended for use by trained healthcare professionals in hospital environments. Parameters include: NIBP, SpO2, PR (pulse rate), TEMP. The F3000 Quick TEMP module is not intended for neonates.	The device is intended to be used for measuring, storing, and reviewing of, and to generate prompts for, multiple physiological parameters of adults and pediatrics (including neonates). The device is intended for use by trained healthcare professionals in hospital environments. Parameters include: NIBP, SpO2, PR (pulse rate), TEMP	Different

	The device is not intended for MRI environments.	The F3000 Quick TEMP module is not intended for neonates. The device is not intended for MRI environments.	
Measurement Parameters	SpO_2, PR, NIBP, TEMP	SpO_2, PR, NIBP, TEMP	Same
Operation mode	Spot-checking, Ward round	Spot-checking, Ward round	Same
SpO2 (EDAN Module)			
Measurement Range	0% to 100%	0% to 100%	Same
Accuracy	Adult /Pediatric (not including neonate): 70% to100% : ±2% 0% to 69%: Undefined Neonate: 70% to100%: ±3% 0% to 69%: Undefined	Adult /Pediatric (not including neonate): 70% to100% : ±2% 0% to 69%: Undefined Neonate: 70% to100%: ±3% 0% to 69%: Undefined	
PR from SpO_2			
Measurement range	25 to 300 bpm	25 to 300 bpm	Same
Accuracy	±2 bpm	±2 bpm	
TEMP (Covidien F3000 Quick Temp Module)			
Measuring range	30°C~43°C	30°C~43°C	Same
Prediction measurement range	35°C~43°C	35°C~43°C	
Sensor type	Oral /axillary /rectal	Oral /axillary /rectal	
Measuring Mode	Direct Mode /Adjusted Mode	Direct Mode /Adjusted Mode	
TEMP (Exergen TAT-5000S-RS232-QR Temp Module)			
Temperature Range	61 to 110°F (15.5 to 43°C)	61 to 110°F (15.5 to 43°C)	Same
Clinical Accuracy	± 0.2°F or 0.1°C Per ASTM E1112	± 0.2°F or 0.1°C Per ASTM E1112	
Arterial Heat Balance Range for Body Temperature	94 to 110°F (34.5 to 43°C)	94 to 110°F (34.5 to 43°C)	
TEMP (HTD8808C Non-contact Infrared Thermometer Temp Module)			
Measurement Range	34 °C to 42.9 °C	34 °C to 43.0 °C	Different
Accuracy	34.0~34.9°C: ± 0.3°C (93.2-94.8°F: ± 0.5°F); 35.0~42.0°C: ± 0.2°C (95.0-107.6°F: ± 0.4°F); 42.1~42.9°C: ± 0.3°C	34.0~34.9°C: ± 0.3°C (93.2-94.8°F: ± 0.5°F); 35.0~42.0°C: ± 0.2°C (95.0-107.6°F: ± 0.4°F); 42.1~43.0°C: ± 0.3°C	

	(107.8-109.2°F: ± 0.5°F);	(107.8-109.2°F: ± 0.5°F);	
TEMP (T100A Internal Forehead TEMP Module)			
Measurement Range	/	34°C~43°C（93.2°F~109.4°F）	Different
Accuracy		±0.3 °C：34.0 °C -34.9 °C； ±0.2 °C：35.0 °C -42.0 °C:； ±0.3 °C：42.1°C -43.0 °C；	
TEMP (FORA IR20B EAR THERMOMETER TEMP Module)			
Displayed Temperature Range	/	89.6°F to 109.4°F (32°C to 43°C)	Different
Accuracy		±0.4°F (±0.2°C) for the range of 96.8°F to 102.2°F (36.0°C to 39.0°C) ±0.5°F (±0.3°C) from 89.6°F to 96.6°F (32.0°C to 35.9°C) and from 102.4°F to 109.4°F (39.1°C to 43.0°C)	
Wi-Fi			
IEEE	802.11b/g/n	802.11b/g/n	Same
Frequency Band	5GHz & 2.4GHz	5GHz & 2.4GHz	
Max. Transmit Power (±2 dBm)	2.4GHz: 17dBm (802.11b DSSS) 17dBm (802.11b CCK) 17dBm (802.11g/n OFDM) 5GHz: 10dBm (802.11g OFDM) 9dBm (802.11n)	2.4GHz: 17dBm (802.11b DSSS) 17dBm (802.11b CCK) 17dBm (802.11g/n OFDM) 5GHz: 10dBm (802.11g OFDM) 9dBm (802.11n)	
E-Link			
Radio Technology	BR, EDR, BLE	BR, EDR, BLE	Same
Frequency Range	2402 MHz ~ 2480 MHz	2402 MHz ~ 2480 MHz	
EDAN-NIBP(ICFUS)			
Principle	Oscillometry	Oscillometry	Same
Measuring parameter	SYS, DIA, MAP, PR	SYS, DIA, MAP, PR	
Measurement Range	Adult Mode:	Adult Mode:	

	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg Pediatric Mode: SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg Neonatal Mode: SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg Pediatric Mode: SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg Neonatal Mode: SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg	
NIBP PR Measurement range	40 bpm to 240 bpm	40 bpm to 240 bpm	
NIBP PR Accuracy	±3 bpm or 3.5%, whichever is greater	±3 bpm or 3.5%, whichever is greater	
EDAN-NIBP(IFAST)			
Principle	/	Oscillometry	Different
Measuring parameter		SYS, DIA, MAP	
Measurement Range		Adult Mode: SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg Pediatric Mode: SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg	
Typical measurement time		iFAST: 15 s (depend on SYS, arm circumference and HR/motion disturbance) (measured with E8 cuff, PR is set as 80 bpm and systolic pressure within 120/80 mmHg)	

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)

iM3s Series Vital Signs Monitor were assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1: 2005/A1: 2012/A2: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.

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 80601-2-30:2018 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 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

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 iM3s Series Vital Signs Monitor are substantially equivalent to the predicate devices.