January 28, 2021

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

Re: K202892
Trade/Device Name: Vital Signs Monitor: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, FLL, DQA, DXN
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,

for LT 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

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.

510(k) Number *(if known)*
K202892

Device Name
Vital Signs Monitor (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. 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.

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

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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:

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Contact person: Alice Yang

Preparing date: September 25, 2020

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) Mindray North America, Accutorr 3 Vital Signs Monitor, K132037 (Primary)
2) Edan Instruments, Inc, Vital signs monitor Model iM3, K180380 (Reference)
3) Edan Instruments, Inc, Patient Monitor Model X8,X10,X12, K192514 (Reference)
4) HeTaiDa Technology Co., Ltd, HTD8808C Non-Contact Infrared Body

Thermometers , K171888 (Reference)

5) Capsule Technologie, SAS, SmartLinx Vitals Plus Patient Monitoring System, K171751(Reference)

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, pediatrics and neonates.

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. 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 Mindray Accutorr 3 Vital Signs Monitor which is intended for spot-checking monitoring physiologic parameters, including Pulse Oximetry (SpO_2), Pulse Rate (PR), Non Invasive Blood Pressure (NIBP) and Temperature (TEMP), on adult, pediatric, and neonatal patients in healthcare facilities by physicians or appropriate medical staff under the direction of physicians.

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

Item	<***Predicate Device***> EDAN Instrument Inc. iM3 Vital Signs Monitor	<***Subject Device***> EDAN Instrument Inc. iM3s series Vital Signs Monitor	**Comparison Result**
Manufacturer/K#	K180380	Current Submission	——
Intended Use			
Description	The monitor is 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 monitor is intended for use by trained healthcare professionals in hospital	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	Similar

	environments. Monitored parameters include: NIBP, SpO2, PR (pulse rate), Quick TEMP/Infrared TEMP. The monitor is not intended for MRI environments.	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.	
Measurement Parameters	SpO_2, PR, NIBP, TEMP	SpO_2, PR, NIBP, TEMP	Same
Operation mode	Monitoring, Spot-checking, Ward Round	Spot-checking, Ward round	Different
SpO2 (EDAN Module)			
Measurement Range	0% to 100%	0% to 100%	Same
Accuracy	Adult/pediatric, non-motion conditions 70 to 100%: ±2 % 0-69% unspecified Neonate 70 to 100%: ±3% 0-69% unspecified	Adult /Pediatric: ±2% (70% to100% SpO_2) Undefined (0% to 69% SpO_2) Neonate: ±3% (70% to100% SpO_2) Undefined (0% to 69% SpO_2)	Same
PR from SpO_2			
Measurement range	25 to 300 bpm	25 to 300 bpm	Same
Accuracy	±2 bpm	±2 bpm	Same
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	Same
Sensor type	Oral /axillary /rectal	Oral /axillary /rectal	Same
Measuring Mode	Direct Mode /Adjusted Mode	Direct Mode /Adjusted Mode	Same
Wi-Fi			
IEEE	802.11b/g/n	802.11b/g/n	Same
Frequency Band	2.4GHz ISM band	**5GHz** & 2.4GHz	Different
Max. Transmit Power (±2 dBm)	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	2.4GHz: 17dBm (802.11b DSSS) 17dBm (802.11b CCK) 17dBm (802.11g/n OFDM) **5GHz:** **10dBm (802.11g OFDM)** **9dBm (802.11n)**	Different

e-Link	Bluetooth Low Energy 4.0	Bluetooth Low Energy 4.0	Same
NIBP-Edan			
Principle	\	Oscillometry	The NIBP module is similar to NIBP module of X series cleared by K192514
Measuring parameter		SYS, DIA, MAP, PR	
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 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	
NIBP PR Accuracy		±3 bpm or 3.5%, whichever is greater	
HTD8808C Non-contact Infrared Thermometer	iM3s series is compatible with HTD8808C Non-contact Infrared Thermometer cleared by K171888		
Exergen TemporalScanner Thermometer TAT5000S	iM3s series is compatible with Exergen TemporalScanner Thermometer TAT5000S cleared by K011291		

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:

- 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.

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 80601-2-30:2009+A1:2013 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.