DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 3, 2017

Edan Instruments, Inc.
c/o Mr. Doug Worth
Sr. Dir. US RA/QA
1200 Crossman Way, Suite 200
Sunnyvale, California 94089

Re: K161056
Trade/Device Name: Telemetry Transmitter, model iT20
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, DSI, MLD, DRT, DQA, BZQ, GXY, DPS, DRG
Dated: December 27, 2016
Received: December 30, 2016

Dear Mr. Doug Worth,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161056

Device Name
Telemetry Transmitter, model iT20

Indications for Use *(Describe)*
The iT20 telemetry transmitter is intended to monitor physiological parameters including: ECG, oxygen saturation of arterial blood (SpO2) and pulse rate (PR) for adults and pediatric patients. The iT20 requires the EDAN MFM-CMS (Central Monitoring Station) to provide full functionality of the device.

The iT20 telemetry transmitter is intended to be used in clinical divisions of hospital environments, including CCU and general wards (as Cardiology Dept.).

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.

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Shekou, Nanshan Shenzhen,

518067 P.R. China

Tel: +86(0755) 26858736

Fax: +1 (408) 418-4059

Contact person: Alice Yang

Preparing date: January 23, 2017

2. Device name and classification:

Device Name: Telemetry Transmitter, model iT20

Model: iT20

Classification Name/ Product code:

870.1025 monitor, physiological, patient(with arrhythmia detection or alarms)/ MHX

870.1025 Detector and Alarm, Arrhythmia/ DSI

870.1025 Monitor, ST Segment with Alarm/ MLD

870.2300 Cardiac monitor (including cardiotachometer and rate alarm)/ DRT

870.2700 Oximeter, Pulse/ DQA

882.1320 Cutaneous electrode/GXY

870.2340 Electrocardiograph/DPS

870.2910 Radiofrequency physiological signal transmitter and receiver/ DRG

Regulatory Class: Class II

3. Predicate Device(s):

1) Shenzhen Mindray Bio-Medical Electronics Co., Ltd, TMS-6016 cleared under K132036.
2) Edan Instruments, Inc. iM70/ K131971

4. Reason for Submission

Introduce a new device iT20.

5. Pre-Submission, IDE

Not applicable, there is no prior submission.

6. Device Description:

iT20 collects physiological parameters by ECG cables and SPO2 sensors, then achieves data analyzing and processing. After that, data will be sent to MFM-CMS via Wi-Fi. The parameters supported are ECG, SPO_2 and PR.

The ECG monitor samples small voltages of about 1 mV that appear on the skin as a result of cardiac activity. Three or five electrodes arranged in standard configurations called leads, are placed on the skin to sense these voltages. At least two electrodes are required for an ECG leads; The third electrode is used as a reference to reduce electrical interference. Each lead presents a heart, producing ECG waveform whose P waves, QRS complex, and T waves vary in amplitude and polarity. The signals from the different leads provide the cardiologist with a complete representation of the electrical activity of the heart, including the HR, which is interpreted as the R-to-R Interval. The timing and wave shape of ECG provides information on

whether the patient's HR is characterized by arrhythmia or other altered functions requiring treatment. The ECG is also used to monitor the effects of infusing antiarrhythmia or cardiotonic agents.

SpO2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO2 measuring unit. The light-electronic transducer in finger sensor converts the pulse red and infrared light modulated by pulse blood oxygen into electrical signal, the signal is processed by hardware and software of the unit. The PLETH curve and numeral value of SpO2 will be obtained.

7. Intended Use/Indications for Use:

The iT20 telemetry transmitter is intended to monitor physiological parameters including: ECG, oxygen saturation of arterial blood (SpO2) and pulse rate (PR) for adults and pediatric patients. The iT20 requires the EDAN MFM-CMS (Central Monitoring Station) to provide full functionality of the device.

The iT20 telemetry transmitter is intended to be used in clinical divisions of hospital environments, including CCU and general wards (as Cardiology Dept.).

8. Predicate Device Comparison

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters improvement, detailed substantial equivalence discussion is included in the following tables.

Comparison to Primary Predicate Device TMS-6016

Item	Proposed device: iT20	Predicate device: TMS-6016	Comparison Result
510(k) Number	**Current Submission**	**K132036**	
Indications for Use			
Intended Use	The iT20 telemetry transmitter is intended to monitor physiological parameters including: ECG, oxygen saturation of arterial blood (SpO2) and pulse rate (PR) for adults and pediatric patients. The iT20 requires the EDAN MFM-CMS (Central Monitoring Station) to provide full functionality of the device. The iT20 telemetry transmitter is intended to be used in clinical divisions of hospital environments, including CCU and general wards (as Cardiology Dept.).	The CMS network transfers information between Hypervisor Central Monitoring System and other networked devices, It also allows information transfer between several CMS. Network connections consist of hardwired network cables and/or WLAN connections. CMS can be used for remote monitor management, storing, printing, reviewing or processing of information from networked devices, and it is operated by medical personnel in hospitals or medical institutions. Telemetry Monitoring System is a sub-system of CMS, intended to obtain ECG and SpO_2 physiological information from adult and pediatric patients, and send it to CMS via WMTS frequency within a defined coverage area.	Similar
ECG Function			
HR Calculation			
Range	ADU: 15 bpm to 300 bpm PED: 15 bpm to 350 bpm	ADU: 15 to 300 bpm PED: 15 to 300 bpm	Similar
Accuracy	±1% or 1 bpm, whichever is greater	±1% or 1 bpm, whichever is greater	Same

Resolution	1 bpm	1bpm	Same
Sensitivity	≥300 μVPP	≥200μVPP	Similar
ST Numeric			
Range	-2.0 mV to +2.0 mV	-2.0 mV to +2.0 mV	Same
Range of Sinus and SV Rhythm			
Bandwidth (-3dB)	Diagnosis: 0.05Hz to 150Hz Monitor: 0.5Hz to 40Hz Surgery: 1Hz to 20Hz	Diagnosis: 0.1 Hz to 40 Hz Monitor:0.5 Hz to 40 Hz Surgery: 1 Hz to 20Hz	Similar
CMRR (Common Mode Rejection Ratio)	Diagnosis: >95dB (the Notch filter is off) Monitor: >105dB (the Notch filter is on) Surgery: >105dB (the Notch filter is on)	105dB(50Hz/60Hz)	Similar
Pace			
Pulse Indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.2 ms to 2.0 ms Ascending time: 10 μs to 100 μs And Amplitude: ±3 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	Amplitude: ±10 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	Similar
Pulse Rejection	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect.	Amplitude: ±10 mV to ±700 mV	

	201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	
SpO_2 Function (EDAN)			
Measurement Range	0-100%	0 to 100 %	Same
Accuracy	Adult /Pediatric :±2 % (70% to 100%) Undefined (0% to 69%)	70 to 100%,±2%(finger sensor, adult) 70 to 100%,±4%(ear sensor) <70% not defined(all sensors)	Similar
Resolution	1 %	1 %	Same
Pulse Rate			
Measuring Range	25 bpm to 300 bpm	18 bpm to 300 bpm	Similar
Accuracy	±2bpm when MR: 25 bpm to 300bpm	±3 bpm when MR: 18 bpm to 100bpm ±6 bpm when MR: 101 bpm to 200bpm ±9 bpm when MR: 201 bpm to 300bpm	Similar
Resolution	1 bpm	1bpm	Same
Electronic Safety			
Anti-electroshock type	Internally powered equipment	Internally powered equipment	Same
Anti-electroshock degree	ECG: CF SpO_2: CF	ECG: CF SpO_2: BF	Similar

Working system	Continuous operation equipment	Continuous operation equipment	Same
Environmental Specifications			
Temperature Range			
Operating	0°C to +40°C	0 to 40°C	Same
Storage including transportation	-20°C to +55°C	-20 to 60°C	Similar
Humidity Range			
Operating	15% to 95% (non-condensing)	15 % to 95 % Relative Humidity (RH)	Same
Storage including transportation	15% to 95% (non-condensing)	10 % to 95 % Relative Humidity (RH)	Similar
Altitude Range			
Operating	86kPa to 106kPa	70.0 to 106.0kPa	Similar
Storage including transportation	70kPa to 106kPa	22.0 to 107.4kPa	
Physical Characteristics			
Weight	<140g(excluding the batteries, ECG leads and SpO_2 module)	<140g(excluding the batteries, ECG leads and SpO_2 module)	Same
Dimensions	100mm x64mm x26mm	62mm x 96mm x 26 mm	Similar
Display Specification			
Description	1.46-inch color screen	Not available	Similar
Resolution	128x128	Not available	
CMS Specification			
NETwork interface	Protocol:IEEE802.3; Speed:10M/100M(self-adaptive) Connector:RJ45	Protocol:IEEE802.3; Speed:10M/100M(self-adaptive) Connector:RJ45	Same

Software Performance	Trend:240-hour for each patient Alarm, event:720 events for each patient	Trend:240-hour for each patient Alarm, event:720 events for each patient	Same
Power Supply			
Power type	Two AA size,1.5V alkaline batteries	Two AA size,1.5V alkaline batteries	Same
Battery voltage range	2V to 3.4VDC	2 to 3.4VDC	
Standard Compliance			
General requirement	IEC 60601-1:2005	IEC 60601-1	Similar
Special requirement	IEC 60601-2-27: 2011	No mention	
	EC13:1991/2002.	EC13:1991/2002	
	ISO 80601-2-61: 2011	No mention	
	IEC 60601-2-49: 2011	No mention	
EMC	IEC 60601-1-2:2007	IEC 60601-1-2:2001 + A1:2004.	
Alarm	IEC 60601-1-8:2006	No mention	
Biocompatibility	Compliance with ISO10993-1 ISO 10993-5,ISO 10993-5-10	Compliance with ISO10993-1 ISO 10993-5,ISO 10993-5-10	
Alarm System			
Alarm Categories	Physiological alarms Technical alarms Prompt information	Physiological alarms Technical alarms Prompt information	Same
Alarm Levels	High level alarms Medium level alarms Low level alarms	High level alarms Medium level alarms Low level alarms	Same

Alarm Modes	Visual alarms Audible alarms Alarm messages Parameter flashes Reminder Tones	Visual alarms Audible alarms Alarm messages Parameter flashes Reminder Tones	Same

Comparison to Reference Device iM70

Item	**Proposed device, iT20**	**Predicate device, iM70**	**Comparison Result**
K#	**Current Submission**	**K131971**	
Wi-Fi			
IEEE	802.11b/g/n	802.11b/g/n	Same
Frequency Band	2.4GHz ISM band	2.4GHz ISM band	Same
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	Same
Typical Transmit Power	13 dBm for 802.11b DSSS 13 dBm for 802.11b CCK 13 dBm for 802.11g/n OFDM	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	Similar

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The main technological differences between the subject and predicate devices are minor differences, and do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical and clinical testing, the different technological characteristics do not affect the safety and effectiveness of the Edan iT20 system.

9. Performance Data:

Non-clinical data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility evaluation

The biocompatibility evaluation for the iT20 Patient Monitor were conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC) / Wireless

Electrical safety and EMC testing were conducted on the iT20 Patient Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 for safety and the IEC 60601-1-2:2007 standard for EMC. Wireless coexistence testing was also performed.

Bench Testing

Bench testing was conducted on the iT20 Patient Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1-8: 2006, IEC 60601-2-27: 2011, IEC 60601-2-49: 2011, ISO 80601-2-61: 2011, ANSI/AAMI EC57: 2012 standards for performance effectiveness.

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." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical data:

Not applicable.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

10. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the iT20 Patient Monitor device should perform as intended in the specified use conditions. The clinical data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject the iT20 Patient Monitor devices are substantially equivalent to the predicate devices.