



Food and Drug Administration
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February 9, 2015

Edan Instruments, Inc
Queena Chen
Certification Engineer
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Nanhai Road 1019#
Shekou, Nanshan Shenzhen
518067 P.R. China

Re: K140579
Trade/Device Name: SD3 Series Ultrasonic Pocket Doppler- SD3 LITE, SD3, SD3 PLUS, SD3 PRO, SD3 VASCULAR
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG, DPW
Dated: January 4, 2015
Received: January 7, 2015

Dear Queena Chen,

This letter corrects our substantially equivalent letter of February 6, 2015.

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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140579

Device Name: SD3 Series Ultrasonic Pocket Doppler
SD3 LITE, SD3, SD3 PLUS, SD3 PRO, SD3 VASCULAR

Intended Use:

The SD3 Series Ultrasonic Pocket Dopplers (hereinafter called “the Doppler”) are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. The 3 MHz waterproof probe is used for more than 9-week gestation and the 2 MHz is used for 12-week gestation. They can also be used to verify fetal heart viability.

The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Prescription Use h Or Over the Counter Use _____.

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter: Edan Instruments, Inc.
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Contact Person: Queena Chen

Prepare date: 2015-02-04

2. Device name and classification: **Device Name:** SD3 series Ultrasonic Pocket Doppler
Model: SD3 LITE, SD3, SD3 PLUS, SD3 PRO, SD3 VASCULAR,
hereinafter called SD3 series

Classification Name:

21 CFR 884.2660 Fetal ultrasonic monitor and accessories

21 CFR 870.2100 Cardiovascular blood flowmeter

Product code: KNG, DPW

Regulatory Class: Class II

3. Premarket Notification Class III Certification and Summary Not applicable, the subject device is Class II.

4. Predicate Device(s): Sonotrax Series Ultrasonic Pocket Doppler / K101960 / Edan Instruments, Inc.

5. Device Description: The SD3 series Ultrasonic Pocket Doppler is a hand-held device for non-invasive measurement and display of fetal heart rate and blood flow velocity utilizing the principle of Doppler shift of an ultrasound. The ultrasound is transmitted from the probe to patient body (maternal abdominal wall), and moves through biophysical objects. The acoustic ultrasound is reflected by blood and moving objects such as the fetal heart. The reflected ultrasound is received by the probe and is converted into electric signals. The waveform data are applied to the CPU for all the digital processing on OLED Display, operation keys. The audio signal is taken off for the routing to the speaker to generate the analogue signals before digital processing. The following probes are supplied

with the SD3 series Ultrasonic Pocket Doppler:

1. 2 MHz for fetal heart rate.
2. 3 MHz for fetal heart rate
3. 4 MHz for detections of arterial and venous blood flow velocity.
4. 5 MHz for detections of arterial and venous blood flow velocity.
5. 8 MHz for detections of arterial and venous blood flow velocity.

The subject device is not a sterilized product, so there is no detailed information about its sterilization status and the shelf life included in the submission.

FHR Performance:

Sensitivity: 9 weeks gestation (3 MHz)
 FHR Measuring Range: 50 bpm ~ 240 bpm
 Resolution: 1 bpm
 Accuracy: ± 2 bpm

6. Indications for Use:

The SD3 Series Ultrasonic Pocket Dopplers (hereinafter called “the Doppler”) are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.

The 2 MHz and/or 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. The 3 MHz waterproof probe is used for more than 9-week gestation and the 2 MHz is used for 12-week gestation. They can also be used to verify fetal heart viability.

The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

7. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device.

The differences between the subject device and predicate device include physical specifications, display type. Please refer to following table. All above differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

Item	SONOTRAX	SD3
Manufacturer/K#	EDAN Instruments/ K101960	EDAN Instruments/ K140579
Intended Use	The Sonotrax series of Ultrasonic Pocket Doppler are intended for use by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and physicians assistants, by prescription from licensed physicians in	The SD3 Series Ultrasonic Pocket Dopplers (hereinafter called “the Doppler”) are intended to be used by health care professionals including registered nurses, practical nurses, midwives, ultrasound technicians, and

	hospitals, clinics and private offices.	physician assistants, by prescription from licensed physicians in hospitals, clinics and private offices.
	The 2 MHz and/ or 3 MHz obstetrical probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. They can also be used to verify fetal heart viability following patient trauma.	The 2 MHz and/or 3 MHz waterproof probes are indicated for the detection of fetal heart rate from early gestation thru delivery and as a general indication of fetal well being. The 3 MHz waterproof probe is used for more than 9-week gestation and the 2 MHz is used for 12-week gestation. They can also be used to verify fetal heart viability.
	The 4 MHz, 5 MHz and/or 8 MHz vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.	The 4 MHz, 5 MHz and/or 8 MHz waterproof vascular probes are indicated for the detection of blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.
Installation and use	hand-held	hand-held
Mode of operation	Continuous operation	Continuous operation
Dimensions	138mm (W) × 85 mm (L) × 32 mm (H)	168mm (W) × 67 mm (L) × 31 mm (H)
Weight	290g	<350 g (including the battery)
Operating:	5°C ~40°C	5°C ~40°C
Transport/Storage:	-20°C ~55°C	-20~55°C
Operating:	25%~85% RH (no condensation)	25% ~ 80%RH (no condensation)
Transport/Storage:	25%~93% RH (no condensation)	25% ~ 93%RH (no condensation)
Operating:	860hPa~1060hPa	860hPa ~1060hPa
Transport/Storage:	700hPa~1060hPa	700hPa ~1060hPa
Type of protection against electric shock	Internally powered equipment	Internally powered equipment
The degree of protection against electric shock	Type B	Type B
The degree of protection against harmful ingress of liquid	The main unit : IPX0, probes : IPX8	The main unit : IPX0, probes : IPX8
The degree of safety of application in the presence of a flammable gas	Equipment not suitable for use in presence of flammable gases	Equipment not suitable for use in presence of flammable gases
The degree of RF	Group 1, Class B	Group 1, Class B
The electrical, mechanical and thermal safety Evaluation	Complies with the standard: IEC 60601-1:2005 IEC 60601-2-37:2007	Complies with the standard: IEC 60601-1:2005 IEC 60601-2-37:2007
EMC Evaluation	Complies with the standard: IEC 60601-1-2:2007	Complies with the standard: IEC 60601-1-2:2007
Software life	Complies with the standard: IEC	Complies with the standard: IEC

cycle processes	62304:2006	62304:2006
Acoustic output Evaluation	Complies with the standard:	Complies with the standard:
	IEC 61157:2007	IEC 61157:2007
	IEC 60601-2-37:2007	IEC 60601-2-37:2007
	NEMA UD 2-2004	NEMA UD 2-2004
Biocompatibility Evaluation	Complies with the standard: ISO 109931-1.	Complies with the standard: ISO 109931-1.
Disinfection	Probe: Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (ethanol 75%, isopropanol alcohol $\leq 70\%$ or glutaraldehyde $\leq 3.6\%$). Wipe the probe with a clean, dry cloth to remove any remaining moisture.	Probe: Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (ethanol 75%, isopropanol alcohol $\leq 70\%$ or glutaraldehyde $\leq 3.6\%$). Wipe the probe with a clean, dry cloth to remove any remaining moisture.
Display	45mm*25mm LCD display	0.96'' OELD double color screen
Battery Supply	2*LR6AA	3*LR6AA 18650 Lithium Battery
Auto Shut down	1 minute after no signal or operation, auto shut down	1 minute after no signal or operation, auto shut down Probe replacement, auto shut down
Resolution	1 bpm	1 bpm
Accuracy	± 3 bpm	± 2 bpm
Sensitivity	10 weeks gestation (3MHz)/ 105.4dB in 200mm distance	9 weeks gestation (3MHz)/ 130dB in 200mm distance
FHR Measuring Range	50bpm ~ 240bpm	50bpm ~ 240bpm
Recording Length	240s	240s

8. Performance Testing:

Non-clinical test:

The following safety standards are conducted on the subject device:

- (1) IEC 60601-1:2005 Safety requirements for medical electrical systems
- (2) IEC 60601-1-2:2007 Electromagnetic compatibility requirements and tests
- (3) AIUM/NEMA UD 2-2004 Acoustic output measurement standard for diagnostic ultrasound equipment
- (4) IEC 60601-2-37:2007 Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- (5) ISO 10993-1:2009, ISO 10993-5:2009 and ISO 10993-10:2010 Biological evaluation of medical devices
- (6) YY0449:2009 Ultrasonic Doppler fetal monitor (a Chinese standard)-Performance requirements and methods of measurement and reporting
- (7) IEC61266:1994 Ultrasonics Hand-held probe Doppler fetal heartbeat detectors—Performance requirements and methods of measurement and reporting

Accuracy of FHR for the SD3 devices was tested with the 2 MHz and 3 MHz probes using an FHR simulator for FHR between 50 and 240 BPM. Testing showed the accuracy met the pre-specified criteria of ± 2 BPM.

Repeatability of FHR measurements for the SD3 devices was shown by taking multiple measurements and comparing with set values on the FHR simulator. A student's T test analysis showed that measurements were repeatable to a 95% confidence.

Clinical test:

Physicians at 6 hospitals used the 2 MHz or the 3 MHz probe depending on the gestational age. There were 162 tests for 11-week to 13-week pregnant women and 99 tests for 9-week to 10(+)-week pregnant women. The test was considered a "pass" if the FHR could be detected and a "fail" if no FHR was detected. A pass rate of 95% was required to support use at a particular gestational age.

Of the 162 cases for the 2 MHz probe from 11-week to 13-week, 157 were considered a "pass." This met the requirements of the test.

Of the 99 cases for the 3 MHz probe for 9-week to 10(+)-week pregnant women, 95 were considered a "pass." This met the requirements of the test.

The subject device passed all testing. The tests were selected to show substantial equivalence between the subject device and the predicate, and since the testing passed, substantial equivalence is shown.

9. Conclusion:

Verification and validation testing was conducted on the SD3 series Ultrasonic Pocket Doppler SD3 series and all testing passed prespecified criteria. This premarket notification submission demonstrates that the Diagnostic Ultrasonic System is substantially equivalent to the predicate devices.