



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Edan Instruments, Inc.  
% Ms. Queena Chen  
Regulatory Engineer  
3/F - B, Nanshan Medical Equipments Park  
Nanhai Road 1019#  
Shenzhen, Guangdong 518067  
CHINA

February 8, 2016

Re: K153475  
Trade/Device Name: SD5 & SD6 Ultrasonic Tabletop Doppler  
Regulation Number: 21 CFR 884.2660  
Regulation Name: Fetal ultrasonic monitor and accessories  
Regulatory Class: II  
Product Code: KNG  
Dated: November 30, 2015  
Received: December 2, 2015

Dear Ms. Chen:

This letter corrects our substantially equivalent letter of January 29, 2016. 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. In the background, there is a faint, large watermark of the letters "FDA".

For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

**K153475**

Device Name

SD5&SD6 Ultrasonic Tabletop Doppler

### Indications for Use (Describe)

The SD5 Ultrasonic TableTop Doppler (hereinafter called "SD5") and SD6 Ultrasonic TableTop Doppler (hereinafter called "SD6") 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 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.

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.

#### **\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRAStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Diagnostic Ultrasound Indications for Use**  
**Ultrasonic Tabletop Doppler SD5**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                             | Mode of Operation |   |     |     |                |                    |                  |
|----------------------|-----------------------------|-------------------|---|-----|-----|----------------|--------------------|------------------|
| General              | Specific                    | B                 | M | PWD | CWD | Colour Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic           | Ophthalmic                  |                   |   |     |     |                |                    |                  |
|                      | Fetal                       |                   |   |     | P   |                |                    |                  |
|                      | Abdominal                   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Specify)   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Neuro)     |                   |   |     |     |                |                    |                  |
|                      | Laparoscopic                |                   |   |     |     |                |                    |                  |
|                      | Pediatric                   |                   |   |     |     |                |                    |                  |
| Fetal                | Small Organ (Specify)       |                   |   |     |     |                |                    |                  |
| Imaging              | Neonatal Cephalic           |                   |   |     |     |                |                    |                  |
| & Other              | Adult Cephalic              |                   |   |     |     |                |                    |                  |
|                      | Trans-rectal                |                   |   |     |     |                |                    |                  |
|                      | Trans-vaginal               |                   |   |     |     |                |                    |                  |
|                      | Trans-urethral              |                   |   |     |     |                |                    |                  |
|                      | Trans-esoph. (Non-Card.)    |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (conventional) |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (superficial)  |                   |   |     |     |                |                    |                  |
|                      | Intra-luminal               |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
|                      | Cardiac Adult               |                   |   |     |     |                |                    |                  |
| Cardiac              | Cardiac Pediatric           |                   |   |     |     |                |                    |                  |
|                      | Trans-Esoph. (Cardiac)      |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
| Peripheral Vessel    | Peripheral vessel           |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |

N = new indication; P=previously licensed

Additional Comments:

---

**Diagnostic Ultrasound Indications for Use**

System: Ultrasonic Tabletop Doppler SD5

Transducer: 2 MHz CW fetal probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                                | Mode of Operation |   |     |     |                   |                       | Other*<br>(Specify) |
|----------------------|--------------------------------|-------------------|---|-----|-----|-------------------|-----------------------|---------------------|
| General              | Specific                       | B                 | M | PWD | CWD | Colour<br>Doppler | Combined<br>(Specify) |                     |
| Ophthalmic           | Ophthalmic                     |                   |   |     |     |                   |                       |                     |
|                      | Fetal                          |                   |   |     | P   |                   |                       |                     |
|                      | Abdominal                      |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative<br>(Specify)   |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative (Neuro)        |                   |   |     |     |                   |                       |                     |
|                      | Laparoscopic                   |                   |   |     |     |                   |                       |                     |
|                      | Pediatric                      |                   |   |     |     |                   |                       |                     |
| Fetal                | Small Organ (Specify)          |                   |   |     |     |                   |                       |                     |
| Imaging              | Neonatal Cephalic              |                   |   |     |     |                   |                       |                     |
| & Other              | Adult Cephalic                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-rectal                   |                   |   |     |     |                   |                       |                     |
|                      | Trans-vaginal                  |                   |   |     |     |                   |                       |                     |
|                      | Trans-urethral                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-esoph.<br>(Non-Card.)    |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(conventional) |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(superficial)  |                   |   |     |     |                   |                       |                     |
|                      | Intra-luminal                  |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
|                      | Cardiac Adult                  |                   |   |     |     |                   |                       |                     |
| Cardiac              | Cardiac Pediatric              |                   |   |     |     |                   |                       |                     |
|                      | Trans-Esoph. (Cardiac)         |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
| Peripheral<br>Vessel | Peripheral vessel              |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |

N = new indication; P=previously licensed

Additional Comments:

**Diagnostic Ultrasound Indications for Use**

System: Ultrasonic Tabletop Doppler SD5

Transducer: 3 MHz CW fetal probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                             | Mode of Operation |   |     |     |                |                    |                  |
|----------------------|-----------------------------|-------------------|---|-----|-----|----------------|--------------------|------------------|
| General              | Specific                    | B                 | M | PWD | CWD | Colour Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic           | Ophthalmic                  |                   |   |     |     |                |                    |                  |
|                      | Fetal                       |                   |   |     | P   |                |                    |                  |
|                      | Abdominal                   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Specify)   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Neuro)     |                   |   |     |     |                |                    |                  |
|                      | Laparoscopic                |                   |   |     |     |                |                    |                  |
|                      | Pediatric                   |                   |   |     |     |                |                    |                  |
| Fetal                | Small Organ (Specify)       |                   |   |     |     |                |                    |                  |
| Imaging              | Neonatal Cephalic           |                   |   |     |     |                |                    |                  |
| & Other              | Adult Cephalic              |                   |   |     |     |                |                    |                  |
|                      | Trans-rectal                |                   |   |     |     |                |                    |                  |
|                      | Trans-vaginal               |                   |   |     |     |                |                    |                  |
|                      | Trans-urethral              |                   |   |     |     |                |                    |                  |
|                      | Trans-esoph. (Non-Card.)    |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (conventional) |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (superficial)  |                   |   |     |     |                |                    |                  |
|                      | Intra-luminal               |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
|                      | Cardiac Adult               |                   |   |     |     |                |                    |                  |
| Cardiac              | Cardiac Pediatric           |                   |   |     |     |                |                    |                  |
|                      | Trans-Esoph. (Cardiac)      |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
| Peripheral Vessel    | Peripheral vessel           |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |

N = new indication; P=previously licensed

Additional Comments:

---

**Diagnostic Ultrasound Indications for Use**  
**Ultrasonic Tabletop Doppler SD6**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                                | Mode of Operation |   |     |     |                   |                       | Other*<br>(Specify) |
|----------------------|--------------------------------|-------------------|---|-----|-----|-------------------|-----------------------|---------------------|
| General              | Specific                       | B                 | M | PWD | CWD | Colour<br>Doppler | Combined<br>(Specify) |                     |
| Ophthalmic           | Ophthalmic                     |                   |   |     |     |                   |                       |                     |
|                      | Fetal                          |                   |   |     | P   |                   |                       |                     |
|                      | Abdominal                      |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative<br>(Specify)   |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative (Neuro)        |                   |   |     |     |                   |                       |                     |
|                      | Laparoscopic                   |                   |   |     |     |                   |                       |                     |
|                      | Pediatric                      |                   |   |     |     |                   |                       |                     |
| Fetal                | Small Organ (Specify)          |                   |   |     |     |                   |                       |                     |
| Imaging              | Neonatal Cephalic              |                   |   |     |     |                   |                       |                     |
| & Other              | Adult Cephalic                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-rectal                   |                   |   |     |     |                   |                       |                     |
|                      | Trans-vaginal                  |                   |   |     |     |                   |                       |                     |
|                      | Trans-urethral                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-esoph.<br>(Non-Card.)    |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(conventional) |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(superficial)  |                   |   |     |     |                   |                       |                     |
|                      | Intra-luminal                  |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
|                      | Cardiac Adult                  |                   |   |     |     |                   |                       |                     |
| Cardiac              | Cardiac Pediatric              |                   |   |     |     |                   |                       |                     |
|                      | Trans-Esoph. (Cardiac)         |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
| Peripheral<br>Vessel | Peripheral vessel              |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |

N = new indication; P=previously licensed

Additional Comments:

---

**Diagnostic Ultrasound Indications for Use**

System: Ultrasonic Tabletop Doppler SD6

Transducer: 2 MHz CW fetal probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                                | Mode of Operation |   |     |     |                   |                       | Other*<br>(Specify) |
|----------------------|--------------------------------|-------------------|---|-----|-----|-------------------|-----------------------|---------------------|
| General              | Specific                       | B                 | M | PWD | CWD | Colour<br>Doppler | Combined<br>(Specify) |                     |
| Ophthalmic           | Ophthalmic                     |                   |   |     |     |                   |                       |                     |
|                      | Fetal                          |                   |   |     | P   |                   |                       |                     |
|                      | Abdominal                      |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative<br>(Specify)   |                   |   |     |     |                   |                       |                     |
|                      | Intra-operative (Neuro)        |                   |   |     |     |                   |                       |                     |
|                      | Laparoscopic                   |                   |   |     |     |                   |                       |                     |
|                      | Pediatric                      |                   |   |     |     |                   |                       |                     |
| Fetal                | Small Organ (Specify)          |                   |   |     |     |                   |                       |                     |
| Imaging              | Neonatal Cephalic              |                   |   |     |     |                   |                       |                     |
| & Other              | Adult Cephalic                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-rectal                   |                   |   |     |     |                   |                       |                     |
|                      | Trans-vaginal                  |                   |   |     |     |                   |                       |                     |
|                      | Trans-urethral                 |                   |   |     |     |                   |                       |                     |
|                      | Trans-esoph.<br>(Non-Card.)    |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(conventional) |                   |   |     |     |                   |                       |                     |
|                      | Musculo-skel<br>(superficial)  |                   |   |     |     |                   |                       |                     |
|                      | Intra-luminal                  |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
|                      | Cardiac Adult                  |                   |   |     |     |                   |                       |                     |
| Cardiac              | Cardiac Pediatric              |                   |   |     |     |                   |                       |                     |
|                      | Trans-Esoph. (Cardiac)         |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |
| Peripheral<br>Vessel | Peripheral vessel              |                   |   |     |     |                   |                       |                     |
|                      | Other (Specify)                |                   |   |     |     |                   |                       |                     |

N = new indication; P=previously licensed

Additional Comments:

**Diagnostic Ultrasound Indications for Use**

System: Ultrasonic Tabletop Doppler SD6

Transducer: 3 MHz CW fetal probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application |                             | Mode of Operation |   |     |     |                |                    |                  |
|----------------------|-----------------------------|-------------------|---|-----|-----|----------------|--------------------|------------------|
| General              | Specific                    | B                 | M | PWD | CWD | Colour Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic           | Ophthalmic                  |                   |   |     |     |                |                    |                  |
|                      | Fetal                       |                   |   |     | P   |                |                    |                  |
|                      | Abdominal                   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Specify)   |                   |   |     |     |                |                    |                  |
|                      | Intra-operative (Neuro)     |                   |   |     |     |                |                    |                  |
|                      | Laparoscopic                |                   |   |     |     |                |                    |                  |
|                      | Pediatric                   |                   |   |     |     |                |                    |                  |
| Fetal                | Small Organ (Specify)       |                   |   |     |     |                |                    |                  |
| Imaging              | Neonatal Cephalic           |                   |   |     |     |                |                    |                  |
| & Other              | Adult Cephalic              |                   |   |     |     |                |                    |                  |
|                      | Trans-rectal                |                   |   |     |     |                |                    |                  |
|                      | Trans-vaginal               |                   |   |     |     |                |                    |                  |
|                      | Trans-urethral              |                   |   |     |     |                |                    |                  |
|                      | Trans-esoph. (Non-Card.)    |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (conventional) |                   |   |     |     |                |                    |                  |
|                      | Musculo-skel (superficial)  |                   |   |     |     |                |                    |                  |
|                      | Intra-luminal               |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
|                      | Cardiac Adult               |                   |   |     |     |                |                    |                  |
| Cardiac              | Cardiac Pediatric           |                   |   |     |     |                |                    |                  |
|                      | Trans-Esoph. (Cardiac)      |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |
| Peripheral Vessel    | Peripheral vessel           |                   |   |     |     |                |                    |                  |
|                      | Other (Specify)             |                   |   |     |     |                |                    |                  |

N = new indication; P=previously licensed

Additional Comments:

---

## 510(k) Summary

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

|                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b><u>1. Submitter:</u></b>                      | Edan Instruments, Inc.<br>3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou,<br>Nanshan Shenzhen, 518067 P.R. China<br>Tel.: (0755) 26858736<br>Fax: (0755) 26882223                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b><u>Contact Person:</u></b>                    | Queena Chen                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b><u>Prepare date:</u></b>                      | 2015-11-30                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b><u>2. Device name and classification:</u></b> | <b>Device Name:</b> Ultrasonic Tabletop Doppler<br><b>Model:</b> SD5, SD6<br><b>Classification Name:</b><br>21 CFR 884.2660 Fetal ultrasonic monitor and accessories<br>Product code: KNG<br><b>Regulatory Class:</b> Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b><u>3. Reason for Submission</u></b>           | Technology Change.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b><u>4. Predicate Device(s):</u></b>            | SD5&SD6 Ultrasonic Tabletop Doppler / K102138 / Edan Instruments, Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b><u>5. Device Description:</u></b>             | <p>The SD5&amp;SD6 Ultrasonic Tabletop Doppler is a hand-held device for non-invasive measurement and display of fetal heart rate 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 LED Display, operation keys. The audio signal is taken off for the routing to the speaker to generate the analogue signals before digital processing. The system is compatible with 2 MHz or 3 MHz for fetal heart rate. The signal acquired can be transferred to SD5 by wired method, and by Bluetooth to SD6.</p> <p>The main unit can be powered by main supply (100 V-240 V~) or Ni-MH Battery (7.2 V/2000 mAh). And transducers are powered by 3.7 V/800 mAh Lithium Battery only.</p> |

## **6. Indications for Use:**

The SD5 Ultrasonic TableTop Doppler (hereinafter called “SD5”) and SD6 Ultrasonic TableTop Doppler (hereinafter called “SD6”) 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 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.

## **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.

Please refer to following table to find differences between the subject device and predicate device. All the 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                                    | SD5/SD6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | SD5/SD6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Comparison Result |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| <b>Manufacturer/K#</b>                  | EDAN Instruments/<br>K102138                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Current Submission                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | ----              |
| <b>Intended Use/Indications for Use</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                   |
| <b>Intended Use/Indications for Use</b> | <p>The SD5 Ultrasonic TableTop Doppler (hereinafter called “SD5”) and SD6 Ultrasonic TableTop Doppler (hereinafter called “SD6”) 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.</p> <p>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.</p> <p>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.</p> | <p>The SD5 Ultrasonic TableTop Doppler (hereinafter called “SD5”) and SD6 Ultrasonic TableTop Doppler (hereinafter called “SD6”) 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.</p> <p>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.</p> | Different         |

| Operation characteristic                                 |                                                                                                                                                                     |                                                                                                                                                                     |           |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Mode of operation                                        | Continuous operation                                                                                                                                                | Continuous operation                                                                                                                                                | Same      |
| Physical Specifications                                  |                                                                                                                                                                     |                                                                                                                                                                     |           |
| Dimensions                                               | Main Unit: 265 mm x 155 mm x 180 mm                                                                                                                                 | Main Unit: 265 mm x 155 mm x 180 mm                                                                                                                                 | Same      |
| Weight                                                   | Main Unit: 1.7 kg (with battery and probe)                                                                                                                          | Main Unit: 1.7 kg (with battery and probe)                                                                                                                          | Same      |
| Display:                                                 | Effective display area: 62.0 mm (W) x 44.0mm(H)<br>Number of characters: 128*64 Dots<br>Dot size: 0.39 mm (W) x 0.55 mm (H)<br>Dot pitch: 0.44 mm (W) x 0.60 mm (H) | Effective display area: 62.0 mm (W) x 44.0mm(H)<br>Number of characters: 128*64 Dots<br>Dot size: 0.39 mm (W) x 0.55 mm (H)<br>Dot pitch: 0.44 mm (W) x 0.60 mm (H) | Same      |
| Environmental Specifications                             |                                                                                                                                                                     |                                                                                                                                                                     |           |
| Working                                                  | Temperature: + 5 °C ~ + 40°C ( +41°F ~ +104°F)<br>Relative Humidity: 25% RH ~ 80% RH (non-condensing)<br>Atmospheric Pressure: 86 kPa ~ 106 kPa                     | Temperature:0°C ~ + 40°C ( +32°F ~ +104°F)<br>Relative Humidity: 15% RH ~ 95% RH (non-condensing)<br>Atmospheric Pressure: 86 kPa ~ 106 kPa                         | Different |
| Transport and Storage                                    | Temperature: -20°C ~ +55°C (-4°F ~ +131°F)<br>Relative Humidity: 25% RH ~ 93% RH (non-condensing)<br>Atmospheric Pressure: 70 kPa ~ 106 kPa                         | Temperature: -20°C ~ +55°C (-4°F ~ +131°F)<br>Relative Humidity: 15% RH ~ 95% RH (non-condensing)<br>Atmospheric Pressure: 70 kPa ~ 106 kPa                         |           |
| Safety Classifications                                   |                                                                                                                                                                     |                                                                                                                                                                     |           |
| Anti-electric Shock Type                                 | Class I equipment with internal power supply                                                                                                                        | Class I equipment with internal power supply                                                                                                                        | Same      |
| Anti-electric Shock Degree                               | Type B applied parts                                                                                                                                                | Type BF applied parts                                                                                                                                               | Different |
| Degree of Protection against Harmful Ingress of Water    | Main Unit: Ordinary equipment (Sealed equipment without liquid proof)<br>Probe: IPX4                                                                                | Main Unit: Ordinary equipment (Sealed equipment without liquid proof)<br>Probe: IPX4                                                                                | Same      |
| Degree of Safety in Presence of Flammable Gases          | Equipment not suitable for use in presence of flammable gases                                                                                                       | Equipment not suitable for use in presence of flammable gases                                                                                                       | Same      |
| The degree of RF                                         | CISPR 11 Group1 Class A                                                                                                                                             | CISPR 11 Group1 Class A                                                                                                                                             | Same      |
| The electrical, mechanical and thermal safety Evaluation | Complies with the standard: IEC 60601-1<br>IEC 60601-2-37                                                                                                           | Complies with the standard: IEC 60601-1<br>IEC 60601-2-37                                                                                                           | Same      |
| EMC Evaluation                                           | Complies with the standard: IEC 60601-1-2                                                                                                                           | Complies with the standard: IEC 60601-1-2                                                                                                                           | Same      |
| Software life cycle processes                            | Complies with the standard: IEC 62304                                                                                                                               | Complies with the standard: IEC 62304                                                                                                                               | Same      |
| Acoustic output Evaluation                               | Complies with the standard: IEC 60601-2-37<br>NEMA UD 2-2004                                                                                                        | Complies with the standard: IEC 60601-2-37<br>NEMA UD 2-2004                                                                                                        | Same      |
| Biocompatibility Evaluation                              | Complies with the standard: ISO 10993-1                                                                                                                             | Complies with the standard: ISO 10993-1                                                                                                                             | Same      |

|                                      |                                                                                      |                                                                                      |           |
|--------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------|
|                                      | ISO 10993-5<br>ISO 10993-10                                                          | ISO 10993-5<br>ISO 10993-10                                                          |           |
| <b>Wireless connection mode(SD6)</b> |                                                                                      |                                                                                      |           |
| <b>Wireless connection mode(SD6)</b> | Infrared                                                                             | Bluetooth                                                                            | Different |
| <b>FHR Specifications</b>            |                                                                                      |                                                                                      |           |
| <b>FHR Specifications</b>            | FHR Measuring Range:<br>50bpm ~ 210bpm<br>Accuracy: $\pm 3$ bpm<br>Resolution: 1 bpm | FHR Measuring Range: 50bpm ~<br>240bpm<br>Accuracy: $\pm 2$ bpm<br>Resolution: 1 bpm | Different |

## **8. Performance Testing:**

### **Non-clinical test:**

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

#### **Biocompatibility testing**

The biocompatibility evaluation for the SD5&SD6 Ultrasonic Tabletop Doppler was 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. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Irritation or Intracutaneous Reactivity

Since The shell of probe and Jacket of wire are identified to that of the F9 Fetal & Maternal Monitor as it was approved in K150901 [06/01/2015] in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc., no new biocompatibility data is provided in this submission.

#### **Electrical safety and electromagnetic compatibility (EMC)**

Electrical safety and EMC testing were conducted on the F series Fetal & Maternal Monitor device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 standards for safety and the IEC 60601-1-2: 2007 for EMC. No changes happened during the testing in order to conform the international standards.

#### **Bench Testing**

Bench testing was conducted on the SD5&SD6 Ultrasonic Tabletop Doppler, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-2-37: 2007.

#### **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 “moderate” level of concern, since a failure or latent flaw in the software will not directly result in serious injury or death to the patient or operator, and the software device is an accessory to a medical device that has a Moderate Level of Concern.

#### **Acoustic testing**

All measurements were conducted in accordance with the measurement procedures of the NEMA Standard Publications UD-2 and following the calibration procedures given in Section 4 of UD-2, and

the reporting requirements of the September 9, 2008 FDA Guide for Track 1.

**Clinical test:**

Not applicable.

**9. Conclusion:**

Verification and validation testing was conducted on the SD5&SD6 Ultrasonic Tabletop Doppler and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the Diagnostic Ultrasonic System is substantially equivalent to the predicate devices.