



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

January 17, 2014

IDT Technology Limited  
C/O Lily Li  
Biomedical Specialist  
Block 33, IDT Technology Limited,  
Chentian Industrial Estate  
Xixiang, Baoan  
Shenzen, China

Re: K131245

Trade/Device Name: Oregon Scientific BLE Upper Arm Blood Pressure Monitor (BPU 321)  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Non-Invasive Blood Pressure Monitor  
Regulatory Class: Class II  
Product Code: DXN  
Dated: Not Dated  
Received: January 14, 2014

Dear Ms. Li:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

**Owen P. Faris -S**

for Bram D. Zuckerman, M.D.  
Division Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



IDT Technology Ltd.

510(k) Number (if known): K131245

Device Name: Blood-pressure meter, Model BPU321

Indications for Use:

By using oscillometric method, the device measure automatically human's Systolic, Diastolic, mean blood pressure, and heart rate. This device is intended for use on adults for age 18 and above. The cuff size is fit for arm circumference of 22-32 cm. The device has the irregular heartbeat indicator feature. The color bar gives a warning signal with readings. The BPU321 can be compatible with the device of Bluetooth Smart-enabled. All values will be read out in LCD panel.

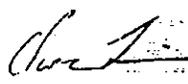
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-the-Counter Use  X

(Optional Format 3-10-98)

 Digitally signed by  
Owen P. Faris -S  
Date: 2014.01.17  
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