National Taiwan University
℅ Pai-Chi Li
Professor
No. 1, Sec. 4, Roosevelt Rd.
Taipei 10617, Taiwan
REPUBLIC OF CHINA

July 11th, 2018

Re: K173486
Trade/Device Name: NTU-USB Ultrasound USB Box
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 20, 2018
Received: June 21, 2018

Dear Pai-Chi 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.

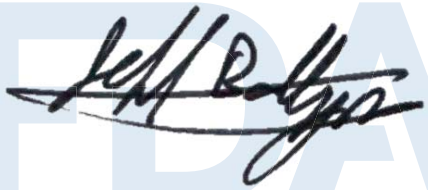
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173486

Device Name

NTU-USB Ultrasound USB Box

Indications for Use *(Describe)*

The NTU-USB ultrasound USB box is a general ultrasound imaging system intended for use by a qualified physician or sonographer for clinical diagnosis. Specific clinical applications and exam types include:

1. Small Organ (Breast)
2. Peripheral Vessel

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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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

Diagnostic Ultrasound Indications For Use Format

System: _NTU-USB Ultrasound USB Box_

Transducer: Qisda L7.5 transducer

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	N*						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							

Clinical Application		Mode of Operation						
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N		N		N		
	Other (Specify)							

N = new indication

Note * : Small Organ is Breast

510(k) Summary

1. Identifying Information

Manufacturer	NTU
Address	No. 1, Sec. 4, Roosevelt Rd., Taipei 10617, Taiwan
Telephone	+886-2-3366-9637
Fax	+886-2-2365-3186
Web	www.ntu-usb.com
E-mail	paichi@ntu.edu.tw
Contact	Pai-Chi Li/ Professor
Name of Device	NTU-USB Ultrasound USB Box

2. Class and Predicate Information

Classification Name	FR. Number	Product Code
Ultrasonic pulsed doppler imaging system	892.1550	IYN
Ultrasonic pulsed echo imaging system	892.1560	IYO
Diagnostic ultrasonic transducer	892.1570	ITX

Common name	Ultrasound USB Box
Proprietary name	NTU-USB
Class	Regulatory Class II
Primary predicate device	LogicScan 128 EXT-1Z Kit (K113184);
Reference device	MicrUs EXT-1H (K161968)

3. Indication for Use

The NTU-USB Ultrasound USB box is a general ultrasound imaging system intended for use by a qualified physician or sonographer for clinical diagnosis. Specific clinical applications and exam types include:

1. Small Organ (Breast)
2. Peripheral Vessel

4. Device Description

The **NTU-USB Ultrasound USB box** is a standalone ultrasound system which can perform real-time anatomical imaging of Small Organs/Parts (e.g. Breast) and blood flow measurements of Peripheral Vascular. Users include ultrasound imaging technicians (sonographers) and physicians. The **NTU-USB Ultrasound USB box** may be used in a hospital (e.g. imaging laboratory, emergency room, patient bedside, operating room), medical clinic, physician's office or a mobile imaging center.

The **NTU-USB Ultrasound USB box** consists of two major components: 1) USB box; and, 2) Transducer. The USB box housed the microprocessor, memory, amplifiers and a power supply for the microprocessor. The USB box performs the calculations involved in processing the data to produce the displayed ultrasound image.
The USB box is designed to connect with a Windows x86platform PC/laptop (not included in this product) and a compatible linear transducer. It receives command and display on the UI of the PC/laptop and following sends electrical currents to and receives electrical pulses from the compatible transducer.

The system provides qualified physicians with a friendly workflow and sufficient image quality for the following applications:

B (2D) mode, ColorDoppler (CD), Pulsed Wave Doppler (PW) mode

Available with the system is a **Linear array transducer** allowing for many clinical applications. Accessories include an **AC adaptor** and a **USB 3.0 cable**. Case studies can be stored to USB memory stick, DVD, and other industry standard archiving devices using the connected PC/laptop.

The NTU-USB ultrasound USB Box contain the hardware and software which collect and pro-process 'rough' data and send it via USB 3.0 connection to a Windows based PC. The main application software is NTU-USB SW running on the PC, it is receiving data, processing and showing image/data on the screen. The main user interface shows an ultrasound image, controls and drop-out menus. The ultrasound images and calculated/measured data can be stored in memory.

5. Performance Standards

The NTU-USB Ultrasound USB box has been designed, manufactured, tested, and certified to comply with the following internationally recognized standards:

- IEC 60601-1:2005+AMD1:2012: Medical electrical equipment part 1: General requirements for safety.
- IEC 60601-1-2:2014: Medical electrical equipment part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-37:2007/AMD1:2015: Amendment 1 - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- NEMA UD 2-2004 (R2009): Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3-2004 (R2009): Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- IEC 62304:2006/AMD1:2015 Amendment 1 - Medical device software - Software life cycle processes

6. General Safety and Effectiveness

The NTU-USB ultrasound USB Box is similar to currently distributed ultrasonic pulsed echo imaging systems. There are no technological characteristics or features or indications for use in this Submission that are not previously evaluated and approved in the predicate devices, nor are there such technologies, features and indications for use not commonly used in the practice of diagnostic ultrasound. The NTU-USB ultrasound USB Box and its accessories are designed for compliance to all applicable medical devices safety standards. Prior release for manufacturing, all such devices, so designed, are tested and determined to be in full compliance with acoustic output, biocompatibility, cleaning and disinfection effectiveness. No additional clinical testing is required, as the indications for use are not a novel indication as shown by the predicate devices in Section 1.5 Predicate Device Comparison. Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time.

7. Patient Contact Material

The material of probe, coming in contact with patient are:

- PC/ABS
- SILICONE

The following biocompatibility standards are conducted on the subject device:
ISO-10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
ISO-10993-5:2009, Biological Evaluation of Medical Devices Part 5: Tests for in vitro cytotoxicity
ISO-10993-10:2010, Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization

8. Conclusion

Verification and validation testing has been conducted on the NTU-USB Ultrasound USB Box. This premarket notification submission demonstrates that the NTU-USB Ultrasound USB Box is substantially equivalent to the predicate devices.