February 20, 2025

Nurodata Inc.
Hao-Ching Chiu
Project Specialist
5F.-3, No. 6-2, Sec.2, Shengyi Rd.
Hsinchu Science Park
Zhubei, 302058
Taiwan

Re: K242681
Trade/Device Name: NUSONO Handheld Ultrasound Scanner (NUSONO-C35); NUSONO Handheld Ultrasound Scanner (NUSONO-L75); NUSONO Handheld Ultrasound Scanner (NUSONO-P25)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 23, 2025
Received: January 23, 2025

Dear Hao-Ching Chiu:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242681

Device Name

NUSONO Handheld Ultrasound Scanner (NUSONO-C35);
NUSONO Handheld Ultrasound Scanner (NUSONO-L75);
NUSONO Handheld Ultrasound Scanner (NUSONO-P25)

Indications for Use *(Describe)*

The NUSONO Handheld Ultrasound Scanner is a portable and software-based ultrasound imaging system, indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
NUSONO-C35
Fetal, Abdominal, Pediatric, Urology, Gynecology, Lung
NUSONO-L75
Pediatric, Small Organ (Thyroid, Prostate, Scrotum, Breast), Musculoskeletal (Superficial and Conventional), Peripheral Vessel, Others (Carotid), Lung
NUSONO-P25
Fetal, Abdominal, Pediatric, Urology, Gynecology, Cardiac (adult and pediatric), Lung

The system provides diagnostic ultrasound imaging in B mode, M mode, Color Doppler mode, Power Doppler mode and combine mode (B+M, B+CD, B+PD), intended for use in environments where healthcare is provided by trained healthcare professionals. The environments where the system can be used include physician offices, clinics, hospitals, and clinical point of care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.

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.

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510(k) Summary

1. Submitter's Information:

Submitter:	Hsien-chen Chiou General Manager Nurodata Inc.
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Fax:	(+886) 3 6588232
Website:	www.nurodata.com
Date prepared:	09/06/2024

2. Name of Device and Class:

Device Name:	NUSONO Handheld Ultrasound Scanner (NUSONO-C35) NUSONO Handheld Ultrasound Scanner (NUSONO-L75) NUSONO Handheld Ultrasound Scanner (NUSONO-P25)
Common Name:	Diagnostic Ultrasound System and Accessories
Classification:	Class II
Panel:	Radiology

Classification Name:

21 CFR Section	Classification Name	Product Code
892.1550	Ultrasonic Pulsed Doppler Imaging System	90 IYN
892.1560	Ultrasonic Pulsed Echo Imaging System	90 IYO
892.1570	Diagnostic Ultrasound Transducer	90 ITX

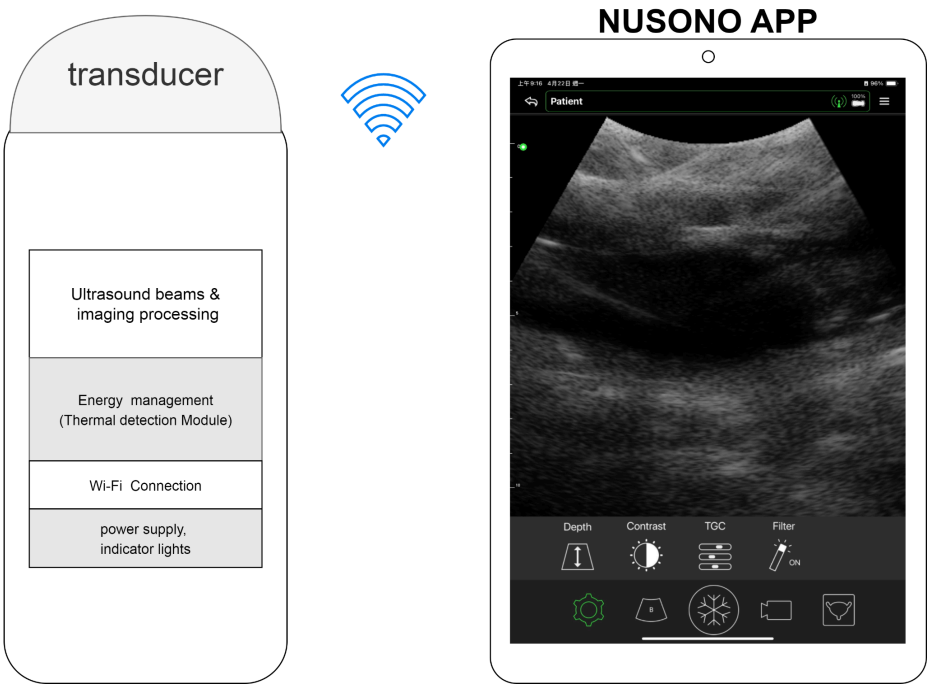
3. Predicate Device:

	Device Name:	510(k) Number:

Primary predicate	Leltek Ultrasound Imaging System (Model: LU700 Series)	K222365
Reference	Clarius Ultrasound Scanner	K192107
Reference	Leltek Ultrasound Imaging System	K191235
Reference	UP600 Diagnostic Doppler Ultrasound System	K121983

4. **Description of the Device:**

The NUSONO Handheld Ultrasound Scanner is a portable, software-controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data through an off-the-self (OTS) iOS 14, 15 and Android 12 or higher versions based mobile device. The system consists of a series of wireless transducers employing Wi-Fi-based technology to communicate with the NUSONO App on traditional smartphone/tablet devices via direct Wi-Fi. The NUSONO App provides the interface for mode/setting control and image display, acquisition, and storage functions. The 128-channel beamformer and image signal processing technology maximize the utility of all imaging transducer elements to enhance the diagnostic utility and confidence provided by the system.



This transportable system is intended for use in environments where healthcare is provided by trained healthcare professionals.

Intended users will be qualified and appropriately trained healthcare professionals with ultrasound.

The NUSONO Handheld Ultrasound Scanner product include:

1. **Scanner models:**
    - NUSONO-C35;
    - NUSONO-L75;
    - NUSONO-P25;
2. **Components:**
    - Software:
        - NUSONO App for iOS 14, 15;
        - NUSONO App for Android 12;
    - Charging dock
    - USB Type-C charging cable
    - Adaptor
3. **Accessories:**
    - Carrying bag
    - Gel dispenser with cap
    - Probe protecting cap of the corresponding probe

5. **Intended Use of the Device:**
Diagnostic ultrasound imaging and fluid flow analysis of the human body.

Indication for Use:
The NUSONO Handheld Ultrasound Scanner is a portable and software-based ultrasound imaging system, indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications:
NUSONO-C35
Fetal, Abdominal, Pediatric, Urology, Gynecology, Lung.
NUSONO-L75
Pediatric, Small Organ (Thyroid, Prostate, Scrotum, Breast), Musculoskeletal (Superficial and Conventional), Peripheral Vessel, Others (Carotid), Lung
NUSONO-P25
Fetal, Abdominal, Pediatric, Urology, Gynecology, Cardiac (adult and pediatric), Lung

The system provides diagnostic ultrasound imaging in B mode, M mode, Color Doppler mode, Power Doppler mode and combine mode (B+M, B+CD, B+PD), intended for use in environments where healthcare is provided by trained healthcare professionals. The environments where the system can be used include physician offices, clinics, hospitals, and clinical point of care for diagnosis of patients except environments where intensity of electromagnetic disturbances is high.

Determination of SE:

The subject device, "NUSONO Handheld Ultrasound Scanner," is a Track 3 system that utilizes the same fundamental scientific technology as the primary predicate device, Leltek Ultrasound Imaging System (K222365), along with the reference devices: Clarius Ultrasound Scanner (K192107), Leltek Ultrasound Imaging System (K191235), and UP600 Diagnostic Doppler Ultrasound System (K121983).

The NUSONO Handheld Ultrasound Scanner shares identical indications for use with the primary predicate device and at least one model of the reference devices. A detailed comparison between the predicate device and the subject device is provided below:

Items	Application device	Primary Predicate device	Reference device	Reference device	Reference device
510k number	Current submission	K222365	K192107	K191235	K121983
Device name	NUSONO Handheld Ultrasound Scanner	Leltek Ultrasound Imaging System (Model: LU700 Series)	Clarius Ultrasound Scanner	Leltek Ultrasound Imaging System	UP600 Diagnostic Doppler Ultrasound System
Product code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX
Intended use	Diagnostic ultrasound imaging and fluid flow analysis of the human body.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	Diagnostic ultrasound imaging and fluid flow analysis.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.	The device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (breast, testes, thyroid), heart

Items	Application device	Primary Predicate device	Reference device	Reference device	Reference device
510k number	Current submission	K222365	K192107	K191235	K121983
					soft tissue, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, Cephalic, Ob/Gyn.
Indications for use	- - Fetal - Abdominal - - Pediatric - Small organ - - - Musculoskeletal (conventional) - Musculoskeletal (superficial) - Urology - Gynecology - Cardiac adult - Cardiac pediatric	- Ophthalmic - Fetal - Abdominal - - Pediatric - Small organ - Neonatal cephalic - - Musculoskeletal (conventional) - Musculoskeletal (superficial) - - - Cardiac adult - Cardiac pediatric	- - Fetal - Abdominal - Intra-operative - Pediatric - - - Adult cephalic - Musculoskeletal (conventional) - - Urology - Gynecology - Cardiac adult - Cardiac pediatric	- - - Abdominal - - - Small organ - - - Musculoskeletal (conventional) - Musculoskeletal (superficial) - - - -	- - - Abdominal - - - - Neonatal cephalic - Adult cephalic - - - - - Cardiac adult - Cardiac pediatric

Items	Application device	Primary Predicate device	Reference device	Reference device	Reference device
510k number	Current submission	K222365	K192107	K191235	K121983
	- Peripheral vessel - Carotid - Lung -	- Peripheral vessel - Carotid - Pulmonary - interventional guidance (includes free hand needle/catheter)	- Peripheral vessel - - -	- Peripheral vessel - - -	- - - -
Modes of operation	- B mode - M mode - Color doppler (CD) - Power doppler (PD) - - - Combined mode (B+M, B+CD, B+PD)	- B mode - M mode - Color doppler (CD) - Power doppler (PD) - PWD - - Combined mode (B+M, B+CD, B+PWD)	- B mode - M mode - Color doppler (CD) - Power doppler (PD) - PWD - - Combined mode (B+M, B+CD, B+PD, B+PWD)	- B mode - M mode - Color doppler (CD) - Power doppler (PD) - PWD - - Combined mode (B+M, B+CD, B+PWD)	- B mode - M mode - Color doppler (CD) - Power doppler (PD) - PWD - CWD - Combined mode (B+M, B+CD, B+PD, B+PWD, B+CD+PD, B+PD+PWD)
Wireless capability	Wi-Fi	Wi-Fi	Wi-Fi Bluetooth	Wi-Fi	N/A
Transducer types	- Convex (NUSONO-C35) - Linear	- - Linear	- Convex (C3 HD) -	- - Linear	- -

Items	Application device	Primary Predicate device	Reference device	Reference device	Reference device
510k number	Current submission	K222365	K192107	K191235	K121983
	(NUSONO-L75) - Phased array (NUSONO-P25)	(LU710L) - Phased array (LU710PA)	-	(LU700L) -	- Phased array (P42)
Power source	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Rechargable battery (Li-ion)	Wall powered
Display	iOS or Android mobile device	iOS or Android mobile device and Windows	iOS or Android mobile device	Android mobile device	Color 15-inch LCD display
510(k) Track	Track 3	Track 3	Track 3	Track 3	Track 3
Standards	- IEC 60601-1 (2020) - IEC 60601-1-2 (2020) - IEC 60601-1-6 (2020) - - IEC 60601-2-37 (2015) - IEC 60601-4-2 (2016) - UD 2-2004 (R2009) - - IEC 62133-2 (2017)	- ANSI/AAMI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - - IEC 60601-2-37 (2015) - - UD 2-2004 (R2009) - UD 3-2004 (R2009) - IEC 62133 (2012)	- ANSI/AAMI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - IEC 60601-1-12 (2014) - IEC 60601-2-37 (2015) - - UD 2-2004 (R2009) - - IEC 62133 (2012)	- ANSI/AAMI ES60601-1 (2012) - IEC 60601-1-2 (2014) - IEC 60601-1-6 (2013) - - IEC 60601-2-37 (2015) - - UD 2-2004 (R2009) - UD 3-2004 (R2009) - IEC 62133 (2012)	- EC 60601-1 EN 60601-1 - EN 60601-1-2 - - - EN 60601-2-37 - - UD 2 - UD 3 -

Items	Application device	Primary Predicate device	Reference device	Reference device	Reference device
510k number	Current submission	K222365	K192107	K191235	K121983
	- IEC 62366-1 (2020) - ISO 10993-1 (2018) - ISO 10993-5 (2009) - ISO 10993-10 (2021) - - ISO 10993-23 (2021) - IEC 62304 (2015) - ISO 15223-1 (2021) - ISO 14971 (2019) - ISO 13485 (2016)	- IEC 62366 (2014) - ISO 10993-1 (2009) - ISO 10993-5 (2009) - ISO 10993-10 (2010) - - - IEC 62304 (2006) - ISO 15223-1 (2016) - ISO 14971 (2019) - ISO 13485 (2016)	- - - ISO 10993-5 (2009) - ISO 10993-10 (2010) - ISO 10993-11 (2017) - - IEC 62304 (2006) - ISO 15223-1 (2012) - ISO 14971 (2007) -	- IEC 62366 (2014) - ISO 10993-1 (2009) - ISO 10993-5 (2009) - ISO 10993-10 (2010) - - - IEC 62304 (2006) - ISO 15223-1 (2016) - ISO 14971 (2019) - ISO 13485 (2016)	- - ISO 10993 - - - - - - - -

6. **Non-clinical Performance Test:**

Non-clinical performance tests include measurement accuracy, system sensitivity, thermal, mechanical, electrical safety, patient-contact materials, cleaning and disinfection, software and acoustic output. Nonclinical performance tests show compliance to the following standards:

Standard	Title of Standard
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical Device Software - Software Life Cycle Processes
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-10 Fourth edition	Biological evaluation of medical devices - Part 10:

2021-11	Tests for Skin Sensitization
ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for Irritation
ISO 11737-1 Third edition 2018-01 [Including AMD1:2021]	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
ISO 13485:2016	Medical Devices - Quality management systems
ISO 14971 Third Edition	Medical devices - Applications of risk management to medical devices
ISO 15223-1 Fourth edition 2021-07	Medical Devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 7000 Sixth edition 2019-07 IEC 60417:2002 DB	Graphical Symbols for Use on Equipment
ISO 7010 Third edition 2019-07	Graphical symbols — Safety colors and safety signs — Registered safety signs
21 CFR 801.109	Code of Federal Regulations Title 21 - FDA - Prescription devices
2002/96/EC (WEEE)	Waste Electrical and Electronic Equipment Directive
IEC TR 60601-4-2 Edition 1.0 2016-05	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
AAMI TIR69:2017/(R2020)	Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
IEEE ANSI USEMCSC C63.27-2021	American National Standard for Evaluation of Wireless Coexistence
ANSI/AAMI SW96:2023	Standard For Medical Device Security - Security Risk Management For Device Manufacturers
ANSI ISA 62443-4-1-2018	Security for industrial automation and control systems Part 4-1: Product security development life-cycle requirements.
AAMI TIR 57:2016	Principles for medical device security - Risk management.

AAMI TIR 97:2019	Principles For Medical Device Security - Postmarket Risk Management For Device Manufacturers
UL ANSI 2900-2-1 First Edition 2017	Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
NIST Cybersecurity Framework (CSF) 2.0	Ver. 2024/02/26
NIST SP 800-53 Rev. 5,	Security and Privacy Controls for Information
IEC 81001-5-1 Edition 1.0 2021-12	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

7. **Clinical Performance Test:**
   The NUSONO Handheld Ultrasound Scanner did not require clinical testing to establish substantial equivalence.

8. **Conclusion:**
   The NUSONO Handheld Ultrasound Scanner is substantially equivalent to the predicate device. The NUSONO Handheld Ultrasound Scanner functions in a manner similar to and is intended for the same use as the predicate device. Based on the predicate device comparison of indications for use, acoustic output and general safety and effectiveness information, as well as the non-clinical performance test results, it is concluded that this device is as safe and effective as the predicate device for its intended use and performance, and is substantially equivalent to the predicate device.

End of Summary