September 27, 2024

Nanosonics Limited
Nancy Kaiser
Regulatory Affairs Manager
7-11 Talavera Road
Macquarie Park, NSW 2113
Australia

Re: K241536
Trade/Device Name: trophon® Wireless Ultrasound Probe Holder
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: OUJ
Dated: May 30, 2024
Received: August 29, 2024

Dear Nancy Kaiser:

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,

Katharine Segars -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and
Infection Control Devices
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.

510(k) Number *(if known)*
K241536

Device Name

trophon® Wireless Ultrasound Probe Holder

Indications for Use *(Describe)*

The trophon Wireless Ultrasound Probe Holder is an accessory to be added to the trophon EPR and trophon2 to allow wireless ultrasound probes to be disinfected.

trophon EPR:
The trophon EPR is designed to provide High-Level Disinfection of ultrasound transducers. The system uses the trophon Disinfectant which is intended to be used exclusively with the trophon EPR device.

The trophon Disinfectant is intended for use as a High-Level Disinfectant to be used exclusively with the trophon EPR for the High-Level Disinfection of ultrasound transducers.

The trophon EPR is suitable for use in general hospital and health care facilities by trained personnel.

The trophon EPR system consists of a multiple use instrument combined with a single use disinfectant, delivered from a multi-dose cartridge.

The trophon Disinfectant should be used with the following contact conditions:
Minimum Operational Cycle Time: 7 minutes
Minimum Concentration: 31.5%
Minimum Disinfectant Dose: 1.0 g
Minimum Chamber Temperature: 56°C

trophon2:
The trophon2 is designed to provide High-Level Disinfection (HLD) of validated ultrasound transducers. High-Level Disinfection is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber contain the ultrasound probe.

The trophon2 system consists of a multiple use instrument combined with a single use disinfectant "trophon Sonex-HL", delivered from a multi-dose cartridge.

The trophon2 is suitable for use in general hospital and health care facilities by trained personnel.

The trophon Sonex-HL should be used with the following contact conditions:
Minimum Operational Cycle Time: 7 minutes
Minimum Concentration: 31.5%
Minimum Disinfectant Dose: 1.0 g
Minimum Chamber Temperature: 56°C

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 – trophon® Wireless Ultrasound Probe Holder

I. DATE PREPARED

September 24, 2024

II. 510(k) NUMBER

K241536

III. 510(k) SUBMITTER

Nanosonics Limited
7-11 Talavera Road
Macquarie Park NSW 2113
Australia

Contact Person: Nancy Kaiser,
Regulatory Affairs Manager
Address: 7-11 Talavera Road
Macquarie Park, NSW 2113
Australia
Email: n.kaiser@nanosonics.com
Telephone: (317) 854-7625

IV. DEVICE

Trade Name of Device:	trophon® Wireless Ultrasound Probe Holder.
Common or Usual Name:	High Level Disinfection Reprocessing Instrument for Ultrasonic Transducers, Mist
Classification:	II
Regulation Number:	21 CFR 892.1570
Product Code:	OUJ

V. PREDICATE DEVICE

Predicate Device

Trade Name:	trophon2
510(k) Number:	K173865
Company Name:	Nanosonics Ltd.

Reference Device

Trade Name:	trophon EPR
510(k) Number:	K103059
Company Name:	Nanosonics Ltd.

VI. DEVICE DESCRIPTION

The trophon Wireless Ultrasound Probe Holder is an accessory to be added to the trophon EPR and trophon2 to allow wireless ultrasound probes to be disinfected.

The Nanosonics trophon EPR and trophon2 are software-controlled devices which provide High- Level Disinfection of ultrasound transducers. The device consists of a sealed disinfection chamber and operates in conjunction with a multi-dose cartridge of concentrated hydrogen peroxide disinfectant, supplied as an accessory to the device. Pre-cleaned and dried ultrasound transducers are placed within the trophon EPR/trophon2

chamber and disinfected by means of an automated disinfection and aeration cycle. The disinfected ultrasound transducer is removed from the chamber and is ready for immediate use.

VII. INDICATIONS FOR USE

The trophon Wireless Ultrasound Probe Holder is an accessory to be added to the trophon EPR and trophon2 to allow wireless ultrasound probes to be disinfected.

trophon EPR:
The trophon EPR is designed to provide High-Level Disinfection of ultrasound transducers. The system uses the trophon Disinfectant which is intended to be used exclusively with the trophon EPR device.
The trophon Disinfectant is intended for use as a High-Level Disinfectant to be used exclusively with the trophon EPR for the High-Level Disinfection of ultrasound transducers.

The trophon EPR is suitable for use in general hospital and health care facilities by trained personnel.

The trophon EPR system consists of a multiple use instrument combined with a single use disinfectant, delivered from a multi-dose cartridge.

The trophon Disinfectant should be used with the following contact conditions:
Minimum Operational Cycle Time: 7 minutes
Minimum Concentration: 31.5%
Minimum Disinfectant Dose: 1.0 g
Minimum Chamber Temperature: 56°C

trophon2:
The trophon2 is designed to provide High-Level Disinfection (HLD) of validated ultrasound transducers. High-Level Disinfection is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber contain the ultrasound probe.

The trophon2 system consists of a multiple use instrument combined with a single use disinfectant "trophon Sonex-HL", delivered from a multi-dose cartridge.

The trophon2 is suitable for use in general hospital and health care facilities by trained personnel.

The trophon Sonex-HL should be used with the following contact conditions:
Minimum Operational Cycle Time: 7 minutes
Minimum Concentration: 31.5%
Minimum Disinfectant Dose: 1.0 g
Minimum Chamber Temperature: 56°C

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The trophon2 and the trophon EPR with the proposed Ultrasound Probe Holder are as safe and as effective in terms of technological characteristics and principles of operation to the predicate device, trophon2 and reference device, trophon EPR without the Ultrasound Probe Holder.

Like the predicate and reference devices, the trophon2 and trophon EPR still achieve HLD by having the probe suspended in their chamber, the Probe Holder is held in place by the cable clamp during high level disinfection to achieve this positioning for a wireless ultrasound probe. During each disinfection cycle, a controlled quantity of hydrogen peroxide mist is generated by a nebulizer and is delivered to the trophon EPR/trophon2 chamber. In the chamber, the mist directly contacts the wired or wireless ultrasound probe covering its surface. Contact occurs for a specified time, temperature, and liquid/mist dosage which determines the germicidal efficacy. The disinfected wired or wireless ultrasound transducer is removed from the chamber and is ready for immediate use. Design verification testing demonstrates that the proposed Wireless Ultrasound Probe Holder meets the product specifications and validation testing confirmed, intended use and user needs continue to be met.

Table 1. A Comparison between the Subject and Predicate Device

Feature	Subject Device: trophon2 (K241536)	Predicate Device: trophon2 (K173865)	Comparison
Manufacturer	Nanosonics Limited	Nanosonics Limited	Same
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	Same
Product Code	OUJ	OUJ	Same
Indication for Use/Intended Use	The trophon Wireless Ultrasound Probe Holder is an accessory to be added to the trophon EPR and trophon2 to allow wireless ultrasound probes to be disinfected. The trophon2 is designed to provide High-level Disinfection (HLD) of validated ultrasound probes, High-Level Disinfection is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber containing the ultrasound probe. The trophon2 is suitable for use in general hospital and health care facilities by trained personnel. The trophon Sonex-HL should be used with the following contact conditions: Minimum Operational Cycle Time: 7 minutes Minimum Concentration: 31.5% Minimum Disinfectant Dose: 1.0 g Minimum Chamber Temperature: 56°C	The trophon2 is designed to provide High-Level Disinfection (HLD) of validated ultrasound transducers. High-Level Disinfection is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber contain the ultrasound probe. The trophon2 system consists of a multiple use instrument combined with a single use disinfectant "trophon Sonex-HL", delivered from a multi-dose cartridge. The trophon2 is suitable for use in general hospital and health care facilities by trained personnel. The trophon Sonex-HL should be used with the following contact conditions: Minimum Operational Cycle Time: 7 minutes Minimum Concentration: 31.5% Minimum Disinfectant Dose: 1.0 g Minimum Chamber Temperature: 56°C	Same

Operating Principle	Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve High -Level Disinfection (HLD)	Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve High -Level Disinfection (HLD)	Same
Disinfectant	trophon Sonex-HL (35% hydrogen peroxide in cartridge)	trophon Sonex-HL (35% hydrogen peroxide in cartridge)	Same
Disinfectant Delivery	Liquid Aerosol Mist	Liquid Aerosol Mist	Same
Disinfectant Removal Process	Automate Aeration	Automate Aeration	Same
Process Monitoring	Automated process monitoring in the device	Automated process monitoring in the device	Same
Chemical Indicator Required?	Yes, trophon chemical indicator (cleared in K103126)	Yes, trophon chemical indicator (cleared in K103126)	Same
Microbiology/Efficacy AOAC Performance Standards	Meets AOAC Methods	Meets AOAC Methods	Same
Device Performance Standards	IEC 601010-1 IEC 61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO 10993-1 ISO 14971	IEC 601010-1 IEC 61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO 10993-1 ISO 14971	Same
Residue Testing	Effectively removes residues from disinfected transducers	Effectively removes residues from disinfected transducers	Same
Chamber Design	Regular shaped chamber	Irregular shaped chamber	Same
Chamber Temperature	Set point 65°C	Set point 75°C	Same
Door Lock	Motor and hook assembly	Motor and hook assembly	Same
Probe Clamp	Spring loaded cleats	Spring loaded cleats	Same
All in One Catalytic Destruct	An integrated catalytic destruct system	An integrated catalytic destruct system	Same
Touch Screen	Color touch screen panel	Color touch screen panel	Same
Software/Firmware	Multiple software/firmware components which are deployed on two PCBAs	Multiple software/firmware components which are deployed on two PCBAs	Same
Traceability	An integrated RFID module allowing automated traceability features in the device. Patient information is not received or recorded by the device; therefore, it cannot be accessed via RFID.	An integrated RFID module allowing automated traceability features in the device. Patient information is not received or recorded by the device; therefore, it cannot be accessed via RFID.	Same
Communication Ports	3 USB ports to connect to external device (i.e. printer) 1 Ethernet port The trophon2 will be able to connect externally to a network via the Ethernet port	3 USB ports to connect to external device (i.e. printer) 1 Ethernet port The trophon2 will be able to connect externally to a network via the Ethernet port	Same
Key Accessories	trophon AcuTrace Operator Card trophon AcuTrace Medical Instrument Tag trophon AcuTrace PLUS activation Card	trophon AcuTrace Operator Card trophon AcuTrace Medical Instrument Tag trophon AcuTrace PLUS activation Card trophon Sonex-HL	Same *An optional Wireless Ultrasound Probe Holder*

	trophon Sonex-HL		*(provided separately) to provide high level disinfection for wireless GE ultrasound probe (model: Vscan Air CL)*
Intended to provide high level disinfection to Wired Probes	Yes	Yes	Same Wired Probes and *Validated Wireless GE Probe (model: Vscan Air CL)*

Table 2. A Comparison between the Subject and Reference Device

Feature	Subject Device: trophon EPR (K241536)	Reference Device: trophon EPR (K103059)	Comparison
Nanosonics Limited	Nanosonics Limited	Nanosonics Limited	Same
Regulation Number	21 CFR 892.1570	21 CFR 892.1570	Same
Product Code	OUJ	OUJ	Same
Indication for Use/Intended Use	The trophon Wireless Ultrasound Probe Holder is an accessory to be added to the trophon EPR and trophon2 to allow wireless ultrasound probes to be disinfected. The trophon EPR is designed to provide High-Level Disinfection of ultrasound transducers. The system uses the trophon Disinfectant which is intended to be used exclusively with the trophon EPR device. The trophon Disinfectant is intended for use as a High-Level Disinfectant to be used exclusively with the trophon EPR for the High-Level Disinfection of ultrasound transducers. The trophon EPR is suitable for use in general hospital and health care facilities by trained personnel. The trophon EPR system consists of a multiple use instrument combined with a single use disinfectant, delivered from a multi-dose cartridge. The trophon Disinfectant should be used with the following contact conditions: Minimum Operational Cycle Time: 7 minutes Minimum Concentration: 31.5% Minimum Disinfectant Dose: 1.0 g Minimum Chamber Temperature: 56°C	The trophon EPR is designed to provide High-Level Disinfection of ultrasound transducers. The system uses the trophon Disinfectant which is intended to be used exclusively with the trophon EPR device. The trophon Disinfectant is intended for use as a High-Level Disinfectant to be used exclusively with the trophon EPR for the High-Level Disinfection of ultrasound transducers. The trophon EPR is suitable for use in general hospital and health care facilities by trained personnel. The trophon EPR system consists of a multiple use instrument combined with a single use disinfectant, delivered from a multi-dose cartridge. The trophon Disinfectant should be used with the following contact conditions: Minimum Operational Cycle Time: 7 minutes Minimum Concentration: 31.5% Minimum Disinfectant Dose: 1.0 g Minimum Chamber Temperature: 56°C	Same

Operating Principle	Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve High - Level Disinfection (HLD)	Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve High -Level Disinfection (HLD)	Same
Disinfectant	trophon Sonex-HL (35% hydrogen peroxide in cartridge)	trophon Sonex-HL (35% hydrogen peroxide in cartridge)	Same
Disinfectant Delivery	Liquid Aerosol Mist	Liquid Aerosol Mist	Same
Disinfectant Removal Process	Automate Aeration	Automate Aeration	Same
Process Monitoring	Automated process monitoring in the device	Automated process monitoring in the device	Same
Chemical Indicator Required?	Yes, trophon chemical indicator (cleared in K103126)	Yes, trophon chemical indicator (cleared in K103126)	Same
Microbiology/Efficacy AOAC Performance Standards	Meets AOAC Methods	Meets AOAC Methods	Same
Device Performance Standards	IEC 601010-1 IEC 61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO 10993-1 ISO 14971	IEC 601010-1 IEC 61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO 10993-1 ISO 14971	Same
Residue Testing	Effectively removes residues from disinfected transducers	Effectively removes residues from disinfected transducers	Same
Chamber Design	Irregular shaped chamber	Irregular shaped chamber	Same
Chamber Temperature	Set point 75˚C	Set point 75˚C	Same
Door Lock	Solenoid	Solenoid	Same
Probe Clamp	Spring clip	Spring clip	Same
All in One Catalytic Destruct	Contains a mist catalytic destruct and liquid catalytic destruct system	Contains a mist catalytic destruct and liquid catalytic destruct system	Same
Touch Screen	A character LCD	A character LCD	Same
Software/Firmware	Single firmware component deployed on the main board PCBA	Single firmware component deployed on the main board PCBA	Same
Traceability	Manually implemented by downloading the trophon EPR device logs during device service or by using the system accessories: trophon Connect, trophon printer and trophon Logbook	Manually implemented by downloading the trophon EPR device logs during device service or by using the system accessories: trophon Connect, trophon printer and trophon Logbook	Same
Communication Ports	1 serial port to connect with external device (trophon printer) No network connectivity in trophon EPR Integration to hospital network is not available	1 serial port to connect with external device (trophon printer) No network connectivity in trophon EPR Integration to hospital network is not available	Same
Key Accessories	trophon Curved Probe Positioner trophon Sonex-HL	trophon Curved Probe Positioner trophon Sonex-HL	Same *An optional Wireless*

			Ultrasound Probe Holder (provided separately) to provide high level disinfection for wireless GE ultrasound probe (model: Vscan Air CL)
Intended to provide high level disinfection to Wired Probes	Yes	Yes	Same Wired Probes and *Validated Wireless GE Probe (model: Vscan Air CL)*

IX. SUMMARY OF NON-CLINICAL TESTING

In support of the substantial equivalence determination, the following non-clinical tests were performed:

Table 3. Summary of Non-clinical Testing

Test	Brief Description	Applicable Standard	Acceptance Criteria	Results (Pass/Fail)
Efficacy Validation	High-level disinfection efficacy was evaluated by simulated use test using Mycobacterium terrae. Inoculation sites included: • Probe touchpoints • Probe scanning windows • Probe button • 3 sites on the Probe Holder including touchpoints (same test methods and acceptance criteria as K103059 and K173865)	N/A	Meets the recommendations of Section III. H.4 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Dimensional	Dimensional assessment (same test methods and acceptance criteria as K103059 and K173865	N/A	The Probe Holder shall have physical dimensions that are accommodated by the trophon2 & EPR chambers.	Pass
Residual Testing	Residual H_2O_2 assessment (same test methods and acceptance criteria as K103059 and K173865	N/A	Meets the recommendations of Section III. I.3 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Material Compatibility	Life-time material compatibility assessment (5000 cycles) (same test methods and	N/A	Meets the recommendations of Section III. J.2 of Content and Format Premarket	Pass

	acceptance criteria as K103059 and K173865)		Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	
Temperature Measurement	Temperature assessment (same test methods and acceptance criteria as K103059 and K173865)	N/A	Probe Holder remains below operating temperature (60°C)	Pass
Leak Test	System leak test performed (same test methods and acceptance criteria as K103059 and K173865)	N/A	Meets the recommendations of Section III. J.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Cleaning Validation	Cleaning test performed per AAMI TIR30:2016 and AAMI ST98:2022 and ISO 15883-5:2021 (E)	AAMI TIR30:2016 and AAMI ST98:2022 and ISO 15883-5:2021 (E)	Meets standards	Pass
Compatibility Test	The Wireless Ultrasound Probe Holder shall withstand 1000 wipe cycles when used with the trophon Companion Cleaning Wipes.	N/A	Meets the recommendations of Section III. J.2a of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Transportation	Simulated transportation testing performed to ensure that packaging and device will not be compromised during shipping.	ASTM D4169-16	Meets standard	Pass
Lifetime Loading	Lifetime loading of Wireless Ultrasound Probe Holder into wireless ultrasound probe	N/A	Meets the recommendations of Section III. J.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Drop Test	Drop test from 1 m height performed per Section 8.3.2 of IEC 61010-1: 2010 + AMD 2016. Ed. 3.1	IEC 61010-1: 2010 + AMD 2016. Ed. 3.1	Meets standard	Pass
Human Factors	A human factors validation study was conducted to ensure that the user interface and workflow are not impacted by the introduction of the subject device.	ANSI AAMI IEC 62366-1:2015+AMD1:2020 ANSI/AAMI HE75:2009/ (R)2013 EN ISO 14971:2019	Meets standards	Pass

X. CLINICAL TESTING

N/A

XI. CONCLUSION

Based on the intended use, technological characteristics and non-clinical testing, the subject device is as safe and as effective and performs at least as safely and effectively as the predicate device.