August 5, 2025

Nanosonics
Nancy Kaiser
n.kaiser@nanosonics.com
7-11 Talavera Road
Macquarie Park, NSW 2113
Australia

Re: K250434
Trade/Device Name: trophon2
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: OUJ
Dated: July 3, 2025
Received: July 3, 2025

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,

Dolly M. Singh -S

Digitally signed by Dolly M. Singh -S
Date: 2025.08.05 09:46:16 -04'00'

For: Katharine Segars
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)*
K250434

Device Name
trophon2

Indications for Use *(Describe)*

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: 4 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.

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:

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"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."

510(k) SUMMARY – trophon2

I. DATE PREPARED

August 5, 2025

II. 510(k) NUMBER

K250434

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:	trophon2
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.

VI. DEVICE DESCRIPTION

The trophon2 is a software-controlled device which provides High- Level Disinfection of validated ultrasound probes. 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 trophon2 chamber and disinfected by means of an automated disinfection and aeration cycle.

VII. INDICATIONS FOR USE

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 containing 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: 4 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 with the proposed software 1.8 is substantially equivalent in terms of technological characteristics, software architecture, and principle of operation to the cleared trophon2.

Like the predicate device, the trophon2 achieves high level disinfection (HLD) by having the probe suspended directly in the chamber (for a wired ultrasound probe) or the Probe Holder is held in place by the cable clamp and suspended in the chamber containing a wireless ultrasound probe during high level disinfection. During each disinfection cycle, a controlled quantity of hydrogen peroxide mist is generated by a nebulizer and is delivered to the 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 prepared for either storage or use as per the trophon2 User Manual.

Software verification and validation testing has been successfully completed using previously identified test methods and the same acceptance criteria as in the predicate device.

Table 1. A Comparison between the Subject and Predicate Device

Feature	Subject Device: trophon2	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
Intended Use	To provide high level disinfection (HLD) of ultrasound probes. HLD is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber containing the ultrasound probe.	To provide high level disinfection (HLD) of ultrasound probes. HLD is achieved by surface exposure to a controlled dose of hydrogen peroxide mist delivered to a disinfection chamber containing the ultrasound probe.	Same
Indication for Use	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 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: *4 minutes* Minimum Concentration: 31.5% Minimum Disinfectant Dose: 1.0 g Minimum Chamber Temperature: 56°C	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 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	Substantially Equivalent
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	Automate Aeration	Automate Aeration	Same

Process			
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 61010-1 IEC 61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO 10993-1 ISO 14971 IEC 60601-1-2 IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version IEC 61010-1 Edition 3.1 2017-01 Consolidated Version IEC 61010-2-040:2021 IEC 62304:2006+AMD1:2015 ISO 27001:2002 ANSI/AAMI SW96:2023 AAMI/ANSI/IEC TIR 80001-2-2:2012	IEC 61010-1 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	Regular shaped chamber	Same
Minimum Chamber Temperature	56 °C	56 °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	trophon AcuTrace Operator	Same

	Card trophon AcuTrace Medical Instrument Tag trophon AcuTrace PLUS activation Card trophon Sonex-HL An optional Wireless Ultrasound Probe Holder (provided separately) to provide high level disinfection for wireless GE ultrasound probe (model no. Vscan Air CL) – cleared in K241536	Card trophon AcuTrace Medical Instrument Tag trophon AcuTrace PLUS activation Card trophon Sonex-HL An optional Wireless Ultrasound Probe Holder (provided separately) to provide high level disinfection for wireless GE ultrasound probe (model no. Vscan Air CL) – cleared in K241536	
Intended to provide high level disinfection to Wired and Wireless Ultrasound Probes	Yes	Yes	Same

IX. SUMMARY OF NON-CLINICAL TESTING

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

Table 2. Summary of Non-clinical Testing

Test	Brief Description	Applicable Standard	Acceptance Criteria	Results (Pass/Fail)
Mycobactericidal Efficacy Test	Potency tests were conducted under worst case conditions per the FDA Guidance "Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	AOAC 6.3.06:2012	Meets the recommendations of Section III. H.5a of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Fungicidal efficacy Test		AOAC 6.3.02:2006		Pass
Bactericidal Efficacy Test		AOAC 6.2.02:2006 AOAC 6.2.03:2006 AOAC 6.2.05:2006		Pass
Virucidal Efficacy Test (Poliovirus type 1)		N/A		Pass
Virucidal Efficacy Test (Herpes simplex virus type 1)		N/A		Pass
Simulated Use Test	Simulated use testing was conducted under worst case conditions per the FDA Guidance "Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants" January 3, 2000	ASTM E1837-96(2014)	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

	(same test methods and acceptance criteria as K173865)			
Critical Process Parameters Validation	1. Temperature Sensor (same test methods and acceptance criteria as K173865)	N/A	The verification sensor temperature is equal to or greater than the lower verification sensor temperature limit at any time during all disinfection cycles at temperature setpoint.	Pass
	2. Dose Sensor vs Consumption Assessment (same test methods and acceptance criteria as K173865)	N/A	The dose limits for a disinfection cycle shall correspond to the defined operational range of the device.	Pass
	3. Dosage Measurement (same test methods and acceptance criteria as K173865)	N/A	Within the upper and lower limits of the dosage sensors corresponding to the defined operational range of the device	Pass
	4. Flow Rate Measurement (same test methods and acceptance criteria as K173865)	N/A	A statistically linear relationship ($R^2 \geq 0.99$) exists between the flow rate and the max nebuliser fan rpm.	Pass
Chamber Venting Assessment	Testing was conducted to verify that venting of the hydrogen peroxide disinfectant from the disinfection chamber prior to the user opening the door. (same test methods and acceptance criteria as K173865)	N/A	Meets the recommendations of Section III.I.2 and III. J.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Chemical Indicator (CI) Assessment	Performance of Chemical Indicator Assessment (same test methods and acceptance criteria as K173865)	N/A	Meets the recommendations of Section III.J.3 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
Residual Testing	Ultrasound Probe Residual H2O2 Assessment (same test methods and acceptance criteria as K173865)	N/A	Meets the recommendations of Section III. I.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants	Pass
	Chemical Indicator Residual H2O2 Assessment (same test methods and			Pass

	acceptance criteria as K173865)			
Leak Test	System leak test performed (same test methods and acceptance criteria as 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

X. CLINICAL TESTING

N/A

XI. CONCLUSION

Based on the intended use, technological characteristics, and conclusions drawn from the non-clinical tests, proposed device is determined to be Substantially Equivalent (SE) to predicate device cleared under K173865.