



April 24, 2018

Nanosonics Limited
Ruth Cremin, Ph.D.
Head of Regulatory Affairs
14 Mars Road
Lane Cove, NSW 2066
Australia

Re: K173865

Trade/Device Name: trophon2
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: OUI
Dated: March 23, 2018
Received: March 26, 2018

Dear Ruth Cremin:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

**Geeta K.
Pamidimukkala -S**

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K173865

Device Name
trophon2

Indications for Use (Describe)

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 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.

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510(k) Summary: K173865

510(k) Owner: Nanosonics Limited
14 Mars Road
Lane Cove, NSW, 2066
Australia
Ph: +61 2 8063 1600
Fax: +61 2 9317 5010

Contact Person: Dr. Frederic Bustos
Head of Regulatory Affairs
Nanosonics Limited
14 Mars Road
Lane Cove, NSW 2066
Ph: +61 2 8063 1600
Fax: +61 2 9317 5010

Brand Name: trophon2

Common Name: Hydrogen Peroxide High-Level Disinfection system for
ultrasound transducers

Classification Name: 21CFR 892.1570 – High Level Disinfection Reprocessing
Instrument for Ultrasonic Transducers, Mist

Product Code: OUJ

Regulatory Class: II

Predicate Devices: Trophon EPR (K103059)
Nanosonics Limited

Date Prepared: April 23, 2018

Description of the Device:

The trophon2 is a software controlled device which provides 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 “trophon Sonex- HL”.

Pre-cleaned and dried ultrasound transducers are placed within the trophon2 chamber and disinfected by means of an automated disinfection and aeration cycle.

The disinfected ultrasound transducer is removed from the chamber, wiped and is ready for immediate use.

Indications for Use:

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 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 |

Detailed Predicate device comparison:

The trophon2 is similar to the legally marketed Trophon EPR manufactured by Nanosonics and cleared under 510(k) K103059.

The trophon Sonex-HL is the same disinfectant that is cleared under K103059.

The trophon2 device and the predicate Trophon EPR use a validated and controlled automated cycle to deliver measured doses of disinfectant to a chamber which contains the pre-cleaned and dried ultrasound transducer requiring disinfection.

Both the trophon EPR and the trophon2 require the use of the Trophon Chemical Indicator to verify for each cycle the correct delivery of the disinfectant.

Intended Use

The intended Use of the trophon2 is the same as the Trophon EPR, they are both intended for the High Level Disinfection of ultrasound probes under the same defined conditions.

Similarities between trophon2 device and the predicate device

- Both the trophon2 device and the predicate Trophon EPR are High-Level Disinfecting systems for Ultrasound transducers.
- Both devices are software controlled electromechanical devices which use a validated, automated cycle to deliver measured dose of hydrogen peroxide disinfectant to a chamber which contains the transducer to be disinfected.
- The trophon2 and predicate both monitor and control the disinfection parameters of time, temperature and dose delivery.
- Both devices are used in general hospital and health care facilities to achieve High-Level Disinfection of ultrasound transducers.
- The same Trophon Chemical indicator (K103126) is used in both devices as a means to confirm delivery of the disinfectant.

Differences between trophon2 device and the Trophon EPR

The difference between the trophon2 and Trophon EPR is the addition of new features and some device modifications to improve the usability of the device, mainly around:

- The Chamber shape – to enable irregular shaped probes to better fit in the chamber.
- RFID Functionality – provides a new traceability features when enabled.
- External Communication – allows integration with Hospital networks and Nanosonics Service database when enabled.
- User Interface Improvements – introduction of a colored touch screen.
- Improved aesthetic.
- Design improvements to sub-assemblies.

Comparison Table

Table 1: Device critical parameters for achieving High Level Disinfection

| Device Critical Parameters for HLD | Trophon EPR (predicate) | trophon 2 | Same/Modified |
|---|------------------------------------|------------------------------------|----------------------|
| Operational Cycle Time | Minimum 7 minutes | Minimum 7 minutes | Same |
| Concentration of hydrogen peroxide | Minimum of 31.5% hydrogen peroxide | Minimum of 31.5% hydrogen peroxide | Same |
| Dosage of hydrogen peroxide | Minimum of 1g | Minimum of 1g | Same |
| Chamber Temperature | Minimum of 56°C | Minimum of 56°C | Same |

Table 2: Comparison of Trophon EPR v trophon 2

| Device Design | Trophon EPR (predicate) | trophon 2 | Same / Modified |
|----------------------------|--|---|-----------------|
| <p>Indications for use</p> | <p>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.</p> <p>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.</p> <p>The Trophon EPR is suitable for use in general hospital and health care facilities by trained personnel.</p> <p>The Trophon EPR system consists of a multiple use instrument combined with a single use disinfectant, delivered from a multi-dose cartridge.</p> <p>The Trophon Disinfectant should be used with the following contact conditions:</p> <p>Minimum Operational Cycle Time: 7 minutes</p> <p>Minimum Concentration: 31.5%</p> | <p>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.</p> <p>The trophon2 system consists of a multiple use instrument combined with a single use disinfectant “trophon Sonex-HL”, delivered from a multi-dose cartridge.</p> <p>The trophon2 is suitable for use in general hospital and health care facilities by trained personnel.</p> <p>The trophon Sonex-HL should be used with the following contact conditions:</p> <p>Minimum Operational Cycle Time: 7 minutes</p> <p>Minimum Concentration: 31.5%</p> <p>Minimum Disinfectant Dose: 1.0 g</p> <p>Minimum Chamber Temperature: 56°C</p> | <p>Same</p> |

| | | | |
|--|---|---|------|
| | Minimum Disinfectant Dose: 1 .0 g Minimum Chamber Temperature: 56°C | | |
| Operating Principle | Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve HLD | Software controlled systems that deliver measured doses of hydrogen peroxide disinfectant to achieve HLD | Same |
| Critical Parameters for HLD | As per Table 1 above—minimum operating conditions | As per Table 1 above—minimum operating conditions | Same |
| Disinfectant | 35% hydrogen peroxide in cartridge | 35% hydrogen peroxide in cartridge | Same |
| Disinfectant delivery | Liquid Aerosol Mist | Liquid Aerosol Mist | Same |
| Disinfectant Removal Process | Automated aeration | Automated aeration | Same |
| Process Monitoring | Automated process monitoring in the device | Automated process monitoring in the device | Same |
| Chemical Indicator | Trophon Chemical Indicator (K103126) | Trophon Chemical Indicator (K103126) | Same |
| Microbiology Efficacy / AOAC Performance Standards | Meets the requirements of Section III.H.5 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants AOAC Methods | Meets the requirements of Section III.H.5 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants AOAC Methods | Same |
| Device Performance Standards | IEC 61010-1 IEC61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO10993 ISO14971 | IEC 61010-1 IEC61010-2-040 IEC 61326 IEC 62304 ISO 62366 -1 and -2 ISO10993 ISO14971 | Same |

| | | | |
|--------------------------------|--|--|-------------|
| Residue Testing | Effectively removes residues from disinfected transducers | Effectively removes residues from disinfected transducers | Same |
| Device/ Material Compatibility | Meets the requirements of Section III. J.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants | Meets the requirements of Section III. J.2 of Content and Format Premarket Notification [510(k)] Submission for Liquid Chemical Sterilants/ High Level Disinfectants | Same |
| Chamber design | Irregular shaped chamber | The trophon 2 chamber has a more regularized shape – the volume, height and depth remains the same. | Modified |
| Chamber temperature | Set point 75°C (167°F) in trophon EPR | Set point 65°C (149°F) in trophon2 | Modified |
| Door lock | Solenoid | Motor and hook assembly | Modified |
| Probe clamp | Spring clip | Spring loaded cleats | Modified |
| All in One Catalytic Destruct | Contains a Mist Catalytic Destruct and Liquid Catalytic Destruct system. | An integrated catalytic destruct system is introduced as an improvement to the manufacturing process | Modified |
| Touch screen | A character LCD | A color touch screen panel | Modified |
| Software/ Firmware | Software controlled system- The Trophon EPR has a single firmware component | Software controlled system - trophon2 is comprised of multiple software/firmware components | Modified |
| Traceability | Traceability can be manually implemented by downloading the Trophon EPR device logs during device service or by using the system accessories: | An integrated RFID module is introduced, allowing automated traceability features in the device. Patient information is not received or recorded by the device, | New Feature |

| | | | |
|---------------------|---|---|----------|
| | Trophon Connect Trophon Printer Trophon Logbook | therefore it cannot be accessed via RFID. | |
| Communication ports | Trophon EPR has 1 serial port to connect with external device i.e trophon printer No network connectivity in trophon EPR | 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. | Modified |

Summary of Non-Clinical Testing:

Non-clinical Testing was performed with the trophon2. The testing that was performed with the trophon2 device included Electromechanical and EMC testing, Biocompatibility, Microbiological Efficacy Testing, Validation testing of process parameters, Materials Compatibility, Stability testing of Sonex-HL and Verification Testing of the Chemical Indicator. The results from these tests demonstrated that the subject device met the acceptance criteria for each non-clinical test.

Conclusion Statement:

The information summarized above demonstrates that trophon2 is substantially equivalent to and is as safe and as effective as the legally marketed predicate device Trophon EPR (K103059), Class II (21CFR892.1570, Product code OUJ).