K103059

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510(k) Summary

FEB 24 2011

510(k) Owner:	Nanosonics Ltd Unit 24 566, Gardeners Rd Alexandria, NSW, 2015 Australia Ph: +61 2 8063 1600 Fax: +61 2 9317 5010
Contact Person:	Mr. Ron Weinberger General Manager – Innovation and Technology Nanosonics Unit 24, 566 Gardeners Road Alexandria, NSW 2015 Ph: +61 2 8063 1600 Fax: +61 2 9317 5010
Brand Name:	Nanosonics Trophon EPR Nanosonics Trophon Disinfectant
Common Name:	Hydrogen Peroxide High-Level Disinfection system for ultrasound transducers
Classification Name:	21 CFR Sec. 892.1570 Diagnostic ultrasonic transducer (accessory to)
Product Code:	~~FEX~~ OUJ
Regulatory Class:	II
Predicate Devices:	CS Medical TD-100 (K051305) Reckitt & Colman Sporox™ (K970230)
Date Prepared:	February 16, 2011

Description of the Device:

The Nanosonics Trophon EPR 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, supplied as an accessory to the device. Pre-cleaned and dried ultrasound transducers are placed within the Trophon EPR 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.

Indications for Use:

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

Summary of Equivalence:

The Nanosonics Trophon EPR is substantially equivalent to the CS Medical TD-100 (K051305). The Trophon Disinfectant Cartridge is substantially equivalent to Sporox™ (K970230).

Both the Trophon EPR and predicates are intended to be used in general hospital and health care facilities to achieve High-Level Disinfection of ultrasound transducers.

The Nanosonics Trophon EPR device and the K051305 predicate 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 EPR and the K051305 predicate device include a means to verify for each cycle, the correct delivery of the disinfectant.

A risk assessment concluded that there were no significant new safety concerns raised by the design of Nanosonics' Trophon EPR and associated disinfectant

Performance Testing:

Potency testing conducted on the Trophon Disinfectant delivered through the Trophon EPR was performed according to relevant AOAC and EPA methods.

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High-Level Disinfection efficacy of the Trophon EPR was validated in a simulated use environment.

Ultrasound transducers used in a clinical setting were disinfected with the Trophon EPR. Bioburden testing was conducted pre- and post disinfection cycle and High-Level Disinfection was achieved in all cases.

A range of materials and transducers were exposed to the Trophon EPR disinfection cycle and were shown to be compatible.

Stability testing showed that the disinfectant retained effective concentration for the duration of the labeled shelf life.

Conclusion:

The information summarized above demonstrates that Nanosonics' Trophon EPR is substantially equivalent to the predicate devices in that it:

- achieves validated High-Level Disinfection; and
- provides equivalent or improved safety, in that it uses smaller quantities of disinfectant, produces no significant residues or hazardous wastes, and has no significant adverse effects on ultrasound transducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ron Weinberger
General Manager
Nanosonics, Limited
Unit 24 566, Gardeners Road
Alexandria, NSW 2015
AUSTRALIA

FEB 24 2011

Re: K103059
Trade/Device Name: Nanosonics Trophon EPR
Regulation Number: 21 CFR 892.7570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: II
Product Code: OUJ
Dated: February 7, 2011
Received: February 9, 2011

Dear Mr. Weinberger:

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.

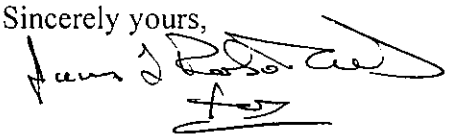
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Nanosonics Trophon EPR

Indications for Use:

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Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use__X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth J. Claire Will

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103059