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510(k) Summary

Date Prepared:	October 20, 2010
Submitter:	Nanosonics Ltd Unit 24 566, Gardeners Rd Alexandria, NSW, 2015 Australia Ph: +61 2 8063 1600 Fax: +61 2 9317 5010
Contact Information:	Mr. Ron Weinberger General Manager – Innovation and Technology Nanosonics Ltd Unit 24, 566 Gardeners Road Alexandria, NSW 2015 Ph: +61 2 8063 1600 Fax: +61 2 9317 5010
Device Trade Name:	Trophon Chemical Indicator
Common or Usual Name:	Chemical Indicator
Device Classification Name:	Chemical Indicator for Liquid Chemical Germicide Physical/Chemical Sterilization Process Indicator
Product Code:	JOJ
Class:	II
Regulation Number:	21 CFR 880.2800
Substantial Equivalence:	The Trophon Chemical Indicator is substantially equivalent to Serim D-CIDE GTA 1.5% Test Strip. (K092346)
Device Description:	The device is a qualitative, single use, disc (26 mm in diameter) that has a hydrogen peroxide sensitive chemical indicating ink applied to a Tyvek substrate. The hydrogen peroxide sensitive chemical indicating ink has been designed to transition from an initial red color to a signal yellow color when subjected to sources of hydrogen peroxide.
Intended Use:	The Trophon Chemical Indicator is intended by Nanosonics for use by health care providers for confirming that the disinfectant delivered into the Chamber of the Nanosonics Trophon EPR disinfector device is above the minimum effective concentration (MEC) required to achieve the stated performance of the Trophon EPR.

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The color of the Trophon Chemical Indicator changes from red to yellow when exposed to hydrogen peroxide, the active ingredient in Trophon EPR-C40 disinfectant. This color change occurs above the minimum effective concentration (MEC) established for this solution.

Conclusion:

The Trophon Chemical Indicator and the predicate device are both single use indicators used to monitor the active ingredient/critical process parameters in a specific solution/process. There are no significant technological risks and no new risks are presented by the design of the Trophon Chemical Indicator.

	Product Comparison **Technological Characteristics**	
	Predicate Device Serim D-CIDE GTA 1.5% Test Strip. (K092346)	**Subject Device** Trophon Chemical Indicator
Description	Chemical indicator based on proprietary ink technology which changes color on exposure to sterilant	Chemical indicator based on proprietary ink technology which changes color on exposure to sterilant
Usage	As indicator to confirm that glutaraldehyde exceeds the validated minimum effective concentration.	As indicator to confirm that hydrogen peroxide exceeds the validated minimum effective concentration.
Indicator Technology	Reacting Chemicals and background dye	Reacting Chemicals and background dye
Nature of Indication	Qualitative – color change	Qualitative – color change
Single Use	Single Use disposable	Single Use disposable
Technical Characteristics	Glutaraldehyde reacts with sodium sulfite to form a colorless addition product and a base. The base then reacts with a pH indicator producing a purple color. The indicator pad also contains sodium bisulfite, which reacts with both glutaraldehyde and with the base.	Hydrogen peroxide reacts with components within the proprietary ink formulation to cause a pH shift, resulting in a color change from an initial red color to a yellow signal color.
User	Trained Health Care Professionals	Trained Health Care Professionals

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-Innovation and Technology
Nanosonics, Limited
Unit 24 566, Gardeners Road
Alexandria, NSW, 2015
Australia

MAR - 3 2011

Re: K103126
Trade/Device Name: Trophon Chemical Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 16, 2011
Received: February 18, 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.

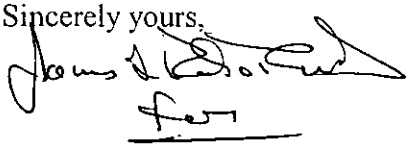
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K103126

510(k) Number (if known):

Device Name: Trophon Chemical Indicator

Indications for Use:

The Trophon Chemical Indicator is used exclusively for monitoring the High Level Disinfection process when placed within the Trophon EPR chamber.

The color of the Trophon Chemical Indicator changes from red to yellow when exposed to hydrogen peroxide, the active ingredient in Trophon EPR-C40 disinfectant. This occurs above the minimum effective concentration (MEC) established for this solution.

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

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

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