



June 26, 2024

True Indicating LLC
Thomas Riha
Cso
946 Kane St
Suite A
Toledo, Ohio 43612

Re: K233413

Trade/Device Name: Ultraphon Chemical Indicator (TRO-T and TRO-B)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 6, 2024
Received: June 6, 2024

Dear Thomas Riha:

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.

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,


Allan Guan -S

For Katie Segars, Ph.D., RAC, PMP, CQA
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233413

Device Name

Ultraphon Chemical Indicator (TRO-T and TRO-B)

Indications for Use (Describe)

The Ultraphon Chemical Indicator is used exclusively for monitoring the High Level Disinfection process when placed within the Nanosonics trophon® EPR and trophon® 2 chambers. The color of the Ultraphon Chemical Indicator changes from red to yellow when exposed to hydrogen peroxide, the active ingredient used in trophon® EPR and trophon® 2 disinfectant. This occurs above the minimum effective concentration (MEC) established for this solution.

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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Prepared on: June 26, 2024

Device Name: Ultraphon Chemical Indicator (TRO-T and TRO-B)

Classification: Class II Medical Device, FDA Product Code JOJ, General Hospital Regulation 21 CFR 880.2800

**Predicate Devices:
(Legally Marketed)** Trophon Chemical Indicator (K103126)

Description of Device: 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 (Product Code: TRO-T) or polypropylene substrate (Product Code: TRO-B). 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.

Indications for Use: The Ultraphon Chemical Indicator is used exclusively for monitoring the High Level Disinfection process when placed within the Nanosonics trophon® EPR and trophon® 2 chambers. The color of the Ultraphon Chemical Indicator changes from red to yellow when exposed to hydrogen peroxide, the active ingredient used in trophon® EPR and trophon® 2 disinfectant. This occurs above the minimum effective concentration (MEC) established for this solution.

Operational Principles: The Ultraphon Chemical Indicator is intended for use within trophon® EPR and trophon2® HLD systems when processing a single ultrasound probe to demonstrate that the probe has been exposed to a hydrogen peroxide high level disinfection cycle and to distinguish between processed and unprocessed cycles.

The Ultraphon Chemical Indicator will transition from an initial color of red (product codes TRO-T and TRO-B) to a yellow signal color when exposed to hydrogen peroxide at a fixed time and temperature within trophon® EPR and trophon2® HLD equipment.

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Technological Characteristic Comparison Table

Feature	Subject Device	Predicate Device (K103126)	Comparison
Intended Use	Chemical indicator for trophon® EPR and trophon® 2 High Level Disinfection	Chemical indicator for trophon® EPR and trophon® 2 High Level Disinfection	Same
Product Code	JOJ	JOJ	Same
FDA Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Same
Indications for Use (IFU)	The Ultraphon Chemical Indicator is used exclusively for monitoring the High Level Disinfection process when placed within the Nanosonics trophon® EPR and trophon® 2 chambers. The color of the Ultraphon Chemical Indicator changes from red to yellow when exposed to hydrogen peroxide, the active ingredient used in trophon® EPR and trophon® 2 disinfectant. This occurs above the minimum effective concentration (MEC) established for this solution.	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.	Similar
Device Design	Product Code TRO-T: Tyvek® (26 mm circle) printed with pH reacting chemical indicator ink Product Code TRO-B: Biaxially Oriented Polypropylene (BOPP) 26 mm circle printed with pH reacting chemical indicator ink	Tyvek® 26 mm circle printed with pH reacting chemical indicator ink	Similar
Indicator Agent	pH reacting chemical and background dye	pH reacting chemical and background dye	Same
Endpoint Specification	Yellow	Yellow	Same
MEC	1.0 gram of 31.5% hydrogen peroxide	1.0 gram of 31.5% hydrogen peroxide	Same
End Point Stability	1 Month	Not Supplied	Similar
Shelf Life	58 Months	16 Months	Similar

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Summary of Nonclinical Testing – Chemical Indicator

Per FDA recognized consensus standards and guidance documents, testing was performed on multiple lots of the subject devices (TRO-T and TRO-B chemical indicators) over their range of shelf life using Nanosonics trophon® EPR and trophon® 2 HLD processes.

- Performance testing was performed per:
 - Guidance for Industry and FDA Reviewers Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/ High Level Disinfectants
<https://www.fda.gov/media/72097/download>.
- End Point Stability of the achieved signal color was evaluated for a period of 30 days (1 month) per:
 - Guidance for Industry and FDA Staff Chemical Indicator (CI) Premarket Notification [510(k)] Submissions <https://www.fda.gov/media/72010/download>.
- Offset-Transference testing was conducted per ISO 11140-1

Summary of Nonclinical Testing Table

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
Performance Testing	Determine if the chemical indicators reach specified endpoint color of yellow and a fail color when exposed to the MEC when combined with a HLD load and exposed to the cycle for which it is intended according to Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff and Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, 2000	<p>Pass result when hydrogen peroxide solution is above the MEC (signal color achieved for all product codes) and fail color when hydrogen peroxide solution is at MEC achieved when exposed to the HLD cycle in combination of a worst-case load:</p> <p style="text-align: center;">trophon® EPR and trophon® 2 HLD Systems</p>	PASS
End Point Stability	Determine the length of time that an exposed Chemical Indicator for hydrogen peroxide retains its post-exposure signal color per Guidance for Industry and Staff – Chemical Indicator (CI) Premarket Notification [510(k)] Submission	1 month	PASS
Offset/Transference	Demonstrate the chemical indicators do not bleed or offset to substrate which it's applied according to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements.	The chemical indicators shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the sterilization cycles for which it is designed.	PASS

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<p>Chemical Indicator Performance Testing in the Presence of Contaminated Ultrasound Probes</p>	<p>Determine exposure color results for product codes TRO-T and TRO-B Chemical Indicators in the presence of contaminated ultrasound probes, when using a Nanosonics trophon® EPR or trophon®2 High Level Disinfection unit per Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, 2000</p>	<p>Hydrogen Peroxide 31.5% (1.8g) More yellow than MEC</p> <p>Hydrogen Peroxide 31.5% (1.0g) Equal to MEC or more red</p>	<p style="text-align: center;">PASS</p>
<p>Color Analysis (X-Rite Spectrophotometer)</p>	<p>Determine the color of Chemical Indicators when detecting H₂O₂ used in Nanosonics trophon® EPR and trophon®2 High Level Disinfection (HLD) exposure cycles by using a spectrophotometer for Pass and Fail compared to MEC per Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, 2000</p>	<ul style="list-style-type: none"> • More yellow than the MEC using 31.5%, 1.8 grams • Equal to or more red than MEC using 31.5%, 1.0 gram • More red than MEC using 31.5%, 0.8 grams • More Yellow than MEC using 31.5%, 1.2 grams 	<p style="text-align: center;">PASS</p>
<p>Sensitivity, Specificity, Accuracy, and Precision of Performance Data</p>	<p>Performance testing data analysis according to the characteristics of Comparative Sensitivity, Analytic Sensitivity, Comparative Sensitivity, Analytic Specificity, Accuracy, and Precision for Chemical Indicators TRO-T and TRO-B when used in Nanosonics trophon® EPR and trophon®2 High Level Disinfection (HLD) exposure cycles per Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, 2000</p>	<p>Comparative Sensitivity: > 0.95</p> <p><u>Analytic Sensitivity (31.5% H₂O₂):</u> 1.8 g H₂O₂ solution: 0.56 – 0.58 g H₂O₂ 1.2 g H₂O₂ solution: 0.37 – 0.39 g H₂O₂ 1.0 g H₂O₂ solution: 0.31 – 0.33 g H₂O₂ 0.8 g H₂O₂ solution: 0.25 – 0.27 g H₂O₂</p> <p>Comparative Specificity: > 0.95</p> <p>Accuracy: > 0.95</p> <p>Precision: < 1 ΔE using X-Rite spectrophotometer</p> <p><u>Analytic Specificity</u> Exposure to Bleach Wipe - Yellow</p> <p>Exposure to Lysol - Yellow</p> <p>Exposure to IPA (70%) - Yellow</p> <p>Dry Heat Exposure 100°C, 15 min - Red</p> <p>UV Exposure – 2 hours - Light Red</p> <p>Ethylene Oxide Exposure 20 min. 54° C 600 ppm, 60%RH - Red</p>	<p style="text-align: center;">PASS</p>

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the Ultraphon Chemical Indicator (TRO-T and TRO-B) is as safe, as effective, and performs as well as or better than the legally marketed predicate, Nanosonics Ltd., Trophon Chemical Indicator (K103126).