April 5, 2024

Terragene SA
% Raymond Kelly
Consultant
Licensale Inc
3422 Leonardo Lane
New Smyrna Beach, Florida 32168

Re: K232103
Trade/Device Name: Terragene® Chemdye® Multivariable Chemical Indicator (CD40), Terragene® Chemdye® Chemical Process Indicator (CD42), Terragene® Cintape® Chemical Process Indicator Tape (CT40)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: QKM, JOJ
Dated: July 10, 2023
Received: July 14, 2023

Dear Raymond Kelly:

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,

Stephen A. Anisko -S
Digitally signed by Stephen A. Anisko -S
Date: 2024.04.05 14:08:35 -04'00'

for: Christopher K. Dugard, MS
Assistant Director
Center for Devices and Radiological Health

OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality

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)*
K232103

Device Name
Terragene® Chemdye® Multivariable Chemical Indicator (CD40), Terragene® Chemdye® Chemical Process Indicator (CD42), Terragene® Cintape® Chemical Process Indicator Tape (CT40)

Indications for Use *(Describe)*

Terragene® Chemdye® Multivariable Chemical Indicator (CD40) is a multivariable chemical indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes in the following systems:
• Sterrad® 100S Sterilization System.
• Sterrad® NX Sterilization System (Standard and Advanced cycles).
• Sterrad® NX with ALLClear® Technology Sterilization System (Standard and Advanced cycles).
• Sterrad® 100NX Sterilization System (Standard, Flex, Express and Duo cycles).
• Sterrad® l00NX with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles).
• V-Pro® maX Low Temperature Sterilization System (Non Lumen, Lumen and Flexible cycles).
• V-Pro® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Non Lumen, Lumen and Flexible cycles).
The chemical indicator changes from purple to green to indicate that the conditions of the cycle have been met.

Terragene® Chemdye® Chemical Process Indicator (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes in the following systems:
• Sterrad® 100S Sterilization System.
• Sterrad® NX Sterilization System (Standard and Advanced cycles).
• Sterrad® NX with ALLClear® Technology Sterilization System (Standard and Advanced cycles).
• Sterrad® 100NX Sterilization System (Standard, Flex, Express and Duo cycles).
• Sterrad® l00NX with ALLClear® Technology Sterilization System (Standard, Flex, Express and Duo cycles).
• V-Pro® maX Low Temperature Sterilization System (Non Lumen, Lumen and Flexible cycles).
• V-Pro® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Non Lumen, Lumen and Flexible cycles).
• Sterizone® VP4 Sterilizer (Cycle 1).
The chemical indicator changes from red to yellow to indicate that the conditions of the cycle have been met.

Terragene® Cintape® Chemical Process Indicator Tape (CT40) is a chemical process indicator tape intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes in the following systems:
• Sterrad® 100S Sterilization System.
• Sterrad® NX Sterilization System (Standard and Advance cycles).
• Sterrad® NX with ALLClear® Technology Sterilization System (Standard and Advanced cycles).
• Sterrad® 100NX Sterilization System (Standard, Flex, Express and Duo cycles).
• Sterrad® l00NX with ALLCrear® Technology Sterilization System (Standard, Flex, Express and Duo cycles).
• V-Pro® maX Low Temperature Sterilization System (Non Lumen, Lumen and Flexible cycles).
• V-Pro® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Non Lumen, Lumen and Flexible cycles).
• Sterizone® VP4 Sterilizer (Cycle 1).
The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."