September 13, 2019

Terragene SA
% Raymond Kelly
Consultant
Licensale Inc
68 Southwoods Terrace
Southbury, Connecticut 06488

Re: K191021
Trade/Device Name: Terragene Bionova® SCBI (BT95, BT96, BT110, BT224); Terragene Bionova® PCD (PCD224-C, PCD224-2); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Integron® (IT12, IT26-1YS, IT26-C, PCD26-C, PCD26-2); Terragene Chemdye® (CD16, CD29, CD40, CD42); Terragene Cintape® (CT22, CT40)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: August 13, 2019
Received: August 16, 2019

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191021

Device Name
Terragene Bionova® SCBI (BT95, BT96, BT110, BT224); Terragene Bionova® PCD (PCD224-C, PCD224-2); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Integron® (IT12, IT26-1YS, IT26-C, PCD26-C, PCD26-2); Terragene Chemdye® (CD16, CD29, CD40, CD42); Terragene Cintape® (CT22, CT40)

Indications for Use *(Describe)*

Terragene Bionova® SCBI (BT224) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of steam sterilization processes. On each Terragene Bionova® SCBI is a chemical process indicator that changes color from pink to brown when exposed to steam.

Terragene Bionova® PCD (PCD224-C, PCD224-2) and Integron® PCD (PCD26-C, PCD26-2) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring and sterilizer qualification testing steam sterilization processes.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60° C and 37° C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Bionova® SCBI (BT110) is a self-contained biological indicator inoculated with viable 10^6 Bacillus atrophaeus bacterial spores and is intended for monitoring the efficacy of ethylene oxide sterilization processes.

The integrator Terragene Integron® IT12 is designed to chemically react over time with the critical parameters of ethylene oxide sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: 55°C for 240 minutes, 600 mg/l, RH 60 %. SV37°C/75 min., SV54°C/30 min, SV55ºC/28 min.

Terragene Chemdye® CD16 is a chemical process indicator intended for monitoring the efficacy of ethylene oxide sterilization processes. The chemical indicator changes from purple/brown to green to indicate that the conditions of the cycle have been met.

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.

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Indications for Use *(Describe)*

Terragene Bionova® SCBI (BT95, BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT95 is Rapid Readout while BT96 is Super Rapid Readout. BT95 has Rapid readout at 2 hours at 60° C while BT96 has Super Rapid readout at 30 minutes at 60° C.

Terragene Chemdye® (CD40, CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from purple to green for CD40 and red to yellow for CD42 to indicate that the conditions of the cycle have been met.

The integrator Terragene Integron® IT26-1YS is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 135° C for 10 minutes; Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes. SV121° C/16.5 min., SV132° C/2.0 min, SV135° C/1.2 min.

The integrator Terragene Integron® IT26-C is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 135° C for 10 minutes; Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes. SV121° C/16.5 min., SV132° C/2.0 min, SV135° C/1.2 min..

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)

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Indications for Use *(Describe)*

Terragene Chemdye® CD29 is a chemical process indicator intended for monitoring the efficacy of steam sterilization processes. The chemical indicator changes from yellow to dark brown/black to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT22 is a chemical process indicator tape intended for monitoring the efficacy of steam sterilization processes. The indicating tape changes from yellow to dark brown/black when exposure to steam.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

Autoclave/Steam Cycles			
Gravity Displacement			
Models	121° C	132° C	135° C
CD29, CT22, IT26-C, IT26-1YS	30 minutes	15 minutes, 25 minutes	10 minutes
PCD26-C, PCD26-2	30 minutes	NA	NA
BT224, PCD224-2, PCD224-C	NA	15 minutes, 25 minutes	10 minutes
BT224, PCD224-2, PCD224-C	NA	10 minutes	10 minutes
Dynamic Air Removal (Vacuum Assist)			
Models	121° C	132° C	135° C
BT224, PCD224-2, PCD224-C, CD29, CT22, IT26-C, IT26-1YS	NA	4 minutes	3 minutes
PCD26-C, PCD26-2	NA	4 minutes	NA

Type of Use *(Select one or both, as applicable)*

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Indications for Use *(Describe)*

Vaporized Hydrogen Peroxide			
Models	Cycles		
BT95, BT96, CT40, CD42	STERRAD 100S 54 minutes		
	STERRAD Standard and Express cycles		
	V-Pro Max and Sterizone VP4		
CD40	STERRAD 100S 54 minutes		
	STERRAD Standard and Express cycles		
	V-Pro Max		
Ethylene Oxide			
Models	Cycles		
CD16, BT110, IT12	55º C for 240 minutes, 600 mg/L, RH 60 %		
Fluorescence Read Time and pH Color Change			
Models	Fluorescence Read Time	pH Color Change	
BT224, PCD224-2, PCD224-C	20 minutes	48 hours	
BT96	30 minutes	48 Hours	
BT95	2 Hours	48 Hours	
BT110	4 hours	48 Hours	
Minimum Stated Values (SV) for Chemical Integrators			
Autoclave/Steam Cycles			
Models	121 ºC	132 ºC	135 ºC
IT26-C, IT26-1YS	16.5 minutes	2.0 minutes	1.2 minutes
Ethylene Oxide (600mg/L)			
Models	37 ºC	54 ºC	55 ºC
IT12	75 minutes	30 minutes	28 minutes

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