DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 2, 2017

Terragene Sa
% Raymond Kelly
Consultant
Licensale Inc
68 Southwoods Ter
Southbury, Connecticut 06488

Re: K163646
Trade/Device Name: Terragene Bionova® SCBI (BT220, BT221, BT222, BT223), Terragene Bionova® PCD (PCD220-C, PCD220-2, PCD222-C, PCD222-2), and Terragene Bionova ® IC10/20FR Reader Incubator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: October 26, 2017
Received: October 31, 2017

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. 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 and Part 809), please contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Tara A. Ryan -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)
K163646

Device Name
Terragene Bionova® SCBI (BT220, BT221, BT222, BT223), Terragene Bionova® PCD (PCD220-C, PCD220-2, PCD222-C, PCD222-2), and Terragene Bionova ® IC10/20FR Reader Incubator

Indications for Use (Describe)
Terragene Bionova® SCBI (BT220, BT221, BT222, BT223) 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 (PCD220-C, PCD220-2, PCD222-C, PCD222-2) provides a defined challenge resistance against the claimed cycles shown below and also demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring and sterilizer qualification testing steam sterilization processes.

Terragene Bionova® IC10/20FR Reader Incubator incubates at 60 °C and reads the Terragene Bionova® SCBI (BT220, BT221, BT222, and BT223) for fluorescent results at 30 minutes (BT223), 1 hour (BT221, BT222), and 3 hours (BT220)

Models	121°C	132°C	135°C
Gravity Displacement			
BT220, BT222, PCD220-C, PCD220-2, PCD222-C, PCD222-2	30 minutes	15 minutes, 25 minutes	10 minutes
BT221, BT223	NA	3 minutes, 10 minutes	3 minutes, 10 minutes
Dynamic Air Removal (Vacuum Assist)			
BT220, BT222, PCD220-C, PCD220-2, PCD222-C, PCD222-2	NA	4 minutes	3 minutes
Models	Fluorescence Read Time		pH Color Change
BT221, BT222, PCD222-C, PCD222-2	1 hour		48 Hours
BT223	30 minutes		48 Hours
BT220, PCD220-C, PCD220-2	3 hours		48 Hours

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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