February 28, 2023

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

Re: K221641
Trade/Device Name: Terragene® Bionova® Hyper Biological Indicator (BT98), Terragene® Bionova® Hyper Auto-reader Incubator (BHY), Terragene® Bionova® NanoBio Auto-reader Incubator (BNB)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC, JOJ
Dated: January 24, 2023
Received: February 3, 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 (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,

Clarence W. Murray III -S

Clarence W. Murray, III, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221641

Device Name
Terragene® Bionova® Hyper Biological Indicator (BT98), Terragene® Bionova® Hyper Auto-reader Incubator (BHY), Terragene® Bionova® NanoBio Auto-reader Incubator (BNB)

Indications for Use *(Describe)*
Terragene® Bionova® Hyper Biological Indicator (BT98) is a self-contained biological indicator (SCBI) inoculated with a minimum of 10^6 viable Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of Plasma or 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® S2 Low Temperature Sterilization System (Fast, Non Lumen, Lumen and Flexible Cycles).
-V-Pro® maX 2 Low Temperature Sterilization System (Fast Non Lumen, Non Lumen, Lumen and Flexible Cycles).

Terragene® Bionova® BT98 has Hyper Rapid readout at 5 minutes at 60 °C.

Terragene® Bionova® Hyper Auto-reader Incubator (BHY) incubates at 60 °C and reads the Terragene® Bionova® Hyper SCBIs at the times prescribed in the User Manual.

Terragene® Bionova® NanoBio Auto-reader Incubator (BNB) incubates at 60 °C and reads the Bionova® SCBIs at the times prescribed in the User Manual.

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.