Terragene SA
% Hernando G. Carrizo
Quality and Process Manager
Ruta Nacional No. 9
Km 280, Parque Industrial Micropi
Alvear, Santa Fe
Argentina

Re: DEN220042
Trade/Device Name: Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH)
Regulation Number: 21 CFR 880.2806
Regulation Name: Biological sterilization indicator with indirect growth detection
Regulatory Class: Class II
Product Code: QVB
Dated: June 29, 2022
Received: July 01, 2022

Dear Hernando G. Carrizo:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH), an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> Terragene® Bionova® Photon Biological Indicator (BT225) is a 7-second readout Self-Contained Biological Indicator (SCBI) inoculated with a minimum of $10^6$ viable *Geobacillus stearothermophilus* bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization processes. BT225 SCBI is not recommended and should not be used for qualification testing purposes. On each Terragene® Bionova® SCBI is a chemical process indicator that changes color from pink to brown when exposed to steam.
>
> - Gravity-displacement Steam Sterilization Cycles
> 132 ºC, 25 minutes
> 132 ºC, 15 minutes
> 132 ºC, 10 minutes
> 135 ºC, 10 minutes
>
> - Dynamic-air-removal Steam Sterilization Cycles

132 ºC, 4 minutes
135 ºC, 3 minutes

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

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH), and substantially equivalent devices of this generic type, into Class II under the generic name biological sterilization indicator with indirect growth detection.

FDA identifies this generic type of device as:

**Biological sterilization indicator with indirect growth detection**. A biological sterilization indicator with indirect growth detection capabilities is a device intended for use by a healthcare provider to accompany products being sterilized through a sterilization process to monitor the adequacy of sterilization. Detection of surviving microorganisms is accomplished by a method other than direct detection of growth or growth products.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On July 01, 2022 , FDA received your De Novo requesting classification of the Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH) can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

| Risks to Health | Mitigation Measures |
|---|---|
| Infection resulting from false negative results for inadequately sterilized devices | Non-clinical performance testing<br>Software verification, validation, and hazard analysis<br>Labeling |
| Delayed or cancelled procedure due to false positive results | Non-clinical performance testing<br>Software verification, validation, and hazard analysis<br>Labeling |
| Electrical shock or interference with other devices | Electrical safety testing<br>Electromagnetic compatibility testing |
| False positive or false negative results due to device degradation in-storage | Shelf life testing |
| Inability to detect growth or growth products due to inadequate incubation conditions, resulting in false negative result. | Non-clinical performance testing |

In combination with the general controls of the FD&C Act, the biological sterilization indicator with indirect growth detection is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and must include the following:
   (i) Demonstration that the measured response is dependent on the sterilization cycle parameter(s) representing the indicated cycle conditions;
   (ii) Analytical performance characteristics validation, including scientifically justified samples, worst case conditions, test protocols, reports, and data analysis to evaluate the indicated cycle conditions with established acceptance criteria for each parameter;
   (iii) Comparison of detected signal with the number of surviving spores using objective performance measures with both sensitivity and specificity parameters.);
   (iv) Limit of detection testing;
   (v) End point color stability testing; and
   (vi) Validation of accuracy over a specified readout time.

(2) Performance data must support the shelf life of the device by demonstrating continued device functionality over the labeled shelf life.

(3) Software verification, validation, and hazard analysis must be performed for any software components of the device.

(4) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the electrical components of the device.

(5) Labeling must include:
   (i) Information on the sensitivity and specificity of the device and warning/precaution statements for any potential false positive or false negative rates;

(ii) Time interval for read out; and
(iii) For devices intended for use in process monitoring only, warnings against use for cycle qualification.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the biological sterilization indicator with indirect growth detection they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Sreekanth Gutala at 301-796-7007.

Sincerely,

Barton Sachs -S
2024.07.12 09:33:59 -04'00'

Bart Sachs, M.D., M.B.A., F.A.C.S.
Acting Deputy Office Director : OHT 4
*for*
Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health