



Terragene SA
% Hernando G. Carrizo
Quality and Process Manager
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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 °C, 25 minutes

132 °C, 15 minutes

132 °C, 10 minutes

135 °C, 10 minutes

- Dynamic-air-removal Steam Sterilization Cycles

Risks to Health	Mitigation Measures
Infection resulting from false negative results for inadequately sterilized devices	Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Delayed or cancelled procedure due to false positive results	Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Electrical shock or interference with other devices	Electrical safety testing 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,

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