August 4, 2025

Terragene
Hernando Carrizo
Quality and Process Manager
Ruta Nacional N° 9, km 280,
Parque Industrial Micropi
Alvear, Santa Fe 2130
Argentina

Re: K251122
Trade/Device Name: Terragene® Bionova® BT20 Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: April 9, 2025
Received: April 11, 2025

Dear Hernando Carrizo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.08.04 17:22:46 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251122

Device Name
Terragene® Bionova® BT20 Biological Indicator

Indications for Use *(Describe)*

Terragene® Bionova® BT20 Biological Indicator is a Self-Contained Biological Indicator (SCBI) intended for routine monitoring of the efficacy of the following steam sterilization processes:

• Gravity-displacement Steam Sterilization Cycles
- 121 °C, 30 minutes
- 132 °C, 25 minutes
- 132 °C, 15 minutes
- 132 °C, 10 minutes
- 134/135 °C, 10 minutes

• Vacuum-assisted Steam Sterilization Cycles
- 121 °C, 20 minutes
- 132 °C, 4 minutes
- 134/135 °C, 3 minutes

Terragene® Bionova® BT20 provides a final result after a 24 hour incubation at 60 ± 2 °C.

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.

510(k) Summary
for
Terragene® Bionova® BT20 Biological Indicator
K251122

Sponsor Information:

Terragene S.A.
Ruta Nacional N° 9, km 280
Parque Industrial Micropi, Alvear
Santa Fe, 2130, Argentina

Contact: Mr. Hernando Carrizo
Quality and Process Manager
Phone Number: +5493415587007
Email: asuntos.regulatorios@terragene.com.ar

Date of Summary: 24 July 2025

1. **Device Name and Classification:**

Common or Usual Name:	Biological Indicator (BI)
Proprietary Name:	Terragene® Bionova® BT20 Biological Indicator
Classification Name:	Indicator, Biological Sterilization Process
Device Classification:	Class II, 21 CFR 880.2800
Product Code:	FRC

2. Predicate Device:

Terragene® Bionova® BT220 SCBI, K163646.

3. Description of Device:

Terragene® Bionova® BT20 Biological Indicators are single-use Self-Contained Biological Indicators (SCBIs) that consist of a polypropylene tube, a filter paper spore carrier inoculated with a minimum of 10^6 viable *Geobacillus stearothermophilus* ATCC® 7953 spores and a glass ampoule containing purple culture medium, enclosed with a plastic colored cap and a barrier permeable to steam. The culture medium contains a pH indicator that changes color upon acidification by the metabolism of living spores. On each BT20 Biological Indicator there is a propylene label printed with a chemical process indicator that changes from pink to brown when exposed to steam.

Final results: 24-hour readout after incubation at 60 °C. If the sterilization process was successful, culture medium will remain purple. If sterilization was not successful, culture medium will turn to yellow during incubation, thus indicating the presence of live *G. stearothermophilus* spores.

4. Indications for Use

Terragene® Bionova® BT20 Biological Indicator is a Self-Contained Biological Indicator (SCBI) intended for routine monitoring of the efficacy of the following steam sterilization processes:

• Gravity-displacement Steam Sterilization Cycles
- 121 °C, 30 minutes
- 132 °C, 25 minutes
- 132 °C, 15 minutes
- 132 °C, 10 minutes
- 134/135 °C, 10 minutes

• Vacuum-assisted Steam Sterilization Cycles
- 121 °C, 20 minutes
- 132 °C, 4 minutes
- 134/135 °C, 3 minutes

Terragene® Bionova® BT20 provides a final result after a 24-hour incubation at 60 ± 2 °C.

5. Comparison of Technological Characteristics with the Predicate Device

The similarities and differences between the subject biological indicator and the predicate device are illustrated in the Device Technological Characteristics Comparison Table (**Table 1**).

Table 1: Device Technological Characteristics Comparison Table

Feature	Subject Device: (K251122)	Predicate Device: (K163646)
Name	Terragene® Bionova® BT20 Biological Indicator	Terragene® Bionova® SCBI BT220
Product Code	FRC	Same
Regulation	880.2800	Same
Class	II	Same
Intended Use	Single Use sterilization process indicator for Steam at 121°C, 132°C, 134° and 135°C	Similar. Single Use sterilization process indicator for Steam at 121°C, 132°C, and 135°C
Indications for Use	Terragene® Bionova® BT20 Biological Indicator is a Self-Contained Biological Indicator (SCBI) intended for routine monitoring of the efficacy of the following steam sterilization processes: • Gravity-displacement Steam Sterilization Cycles - 121 °C, 30 minutes - 132 °C, 25 minutes - 132 °C, 15 minutes - 132 °C, 10 minutes - 134/135 °C, 10 minutes • Vacuum-assisted Steam Sterilization Cycles - 121 °C, 20 minutes - 132 °C, 4 minutes - 134/135 °C, 3 minutes Terragene® Bionova® BT20 provides a final result after a 24-hour incubation at 60 ± 2 °C.	Similar. Terragene® Bionova® SCBI (BT220) is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of Steam sterilization processes. • Gravity-displacement Steam Sterilization Cycles - 121 °C, 30 minutes - 132 °C, 25 minutes - 132 °C, 15 minutes - 135 °C, 10 minutes • Vacuum-assisted Steam Sterilization Cycles - 132 °C, 4 minutes - 135 °C, 3 minutes Fluorescence Read Time: 3 hours. pH Color Change: 48 hours.
Construction	Vial, brown cap, paper filter of the cap, paper spore carrier, glass ampoule with growth media including a pH indicator	Similar. Vial, brown cap, paper filter of the cap, paper spore carrier, glass ampoule with growth media including a pH indicator and a non-fluorescent substrate, 4-methylumbelliferyl-α-D-glucoside (MUG)

Principle of Operation	The device consists of a known number of microorganisms, of a known resistance to the sterilization method and a glass ampoule containing culture medium. The medium contains a pH indicator that changes color upon acidification by the metabolic activity of living spores. Subsequent growth or failure to grow of the microorganisms under suitable conditions indicates the adequacy of sterilization.	Similar. In addition to the visual color change, BT220 also features a 3-hour fluorescence readout based on the α-glucosidase activity, an enzyme associated to *Geobacillus stearothermophilus* spores. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure.
Type of BI	Self-Contained Biological Indicator	Same
Organism (Spore, Species, Strain)	*Geobacillus stearothermophilus* ATCC® 7953	Same
Viable spore population	≥10^6 spores per vial	Same
Resistance Characteristics	D-value$_{121\,°C}$: ≥ 1.5 minutes D-value$_{132\,°C}$: ≥ 10 seconds D-value$_{135\,°C}$: ≥ 8 seconds	Same
Carrier material	Paper	Same
Culture medium color change	If sterilization process is not successful, indicator medium will turn yellow after incubation. If sterilization process was successful, indicator medium will remain purple after incubation.	Same
Chemical Indicator (SCBI Label)	Type 1 process indicator per ISO 11140-1 that changes color to indicate exposure to steam; changes from pink towards brown.	Same. Identical chemical process indicator ink, location, substrate (label), and visual interpretation.
Biological Indicator Incubation Temperature	60 ± 2 ºC	Same
Reduced Incubation Time	Visual color change following 24-hour incubation	Visual color change following 48-hour incubation
Sterile	Non-sterile	Same
Shelf Life	2 years	Same

Both subject and predicate devices have similar intended use and indications for use. This submission introduces a reduced incubation that is supported by performance testing. They are Self-Contained Biological Indicators (SCBIs) made up with the same organism. Subject and predicate devices have same specifications for spore population, resistance characteristics and temperature of incubation. Subject and predicate devices have the same shelf-life. In addition, the predicate device has a chemical indicator printed on the label, which is identical in material, color transition, and function to the CI on the subject device. The subject and predicate devices operate on the same principle. The only difference is that the predicate device can also monitor the sterilization process efficacy via fluorescence readout.

6. Nonclinical Comparison to the Predicate Device

The differences between the submission and predicate devices have been evaluated through performance tests for the Terragene® Bionova® BT20 Biological Indicator.

Performance of the Terragene® Bionova® BT20 Biological Indicator was verified through the following tests:

Test Performed	Applicable Standards	Purpose	Acceptance Criteria	Results
Viable Spore Population Assay	*ISO 11138-1:2017, ISO 11138-3:2017,* and the *FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007.*	Demonstrate that the product Bionova® BT20 meets specifications for spore population ($\geq 10^5$ CFU/BI unit).	Bionova® BT20 should meet specifications for spore population (50 to 300 % of the manufacturer's stated nominal population) according to ISO 11138-1:2017 standard, for the three batches analyzed. Bionova® BT20 should meet specifications for spore population ($\geq 10^5$ CFU/BI unit) according to the FDA Guidance for Industry and FDA Staff "Biological Indicator (BI) Premarket Notification [510(k)] Submissions", and ISO 11138-3:2017 standard, for the three batches analyzed.	Passed
Resistance Characteristics Study	*ISO 11138-1:2017, ISO 11138-3:2017,* and the *FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007.*	Evaluate the resistance characteristics of Bionova® BT20 Biological Indicator. To achieve this aim, four parameters were determined: D-value; Z-value; Survival Time; Kill Time.	D-value should not be lower than 1.5 minutes at 121 °C. D-value should not be lower than 10 seconds at 132 °C. D-value should not be lower than 8 seconds at 134 or 135 °C. Z-value should not be lower than 10 °C. *Minimum Expected Survival Time* should not be lower than 5 minutes at 121 °C. *Minimum Expected Survival Time* should not be lower than 1 minute at 132 °C. *Minimum Expected Survival Time* should not be lower than 40 seconds at 134 or 135 °C No negative results should be obtained for Bionova® BT20 SCBIs exposed to the *Minimum Expected Survival Time.* No positive results should be obtained for Bionova® BT20 SCBIs exposed to the *Maximum Expected Kill Time.*	Passed
Recovery Protocols: Recovery Medium Test	*ISO 11138-1:2017 standard.*	Test suitability of the culture medium used in the build-up of Bionova® BT20 Biological Indicator.	All the inoculated samples should show a positive result (culture medium color change from purple to yellow) after a 7-day incubation at 60 °C. Negative controls (uninoculated samples) should show a negative result (culture medium remaining purple) after a 7-day incubation at 60 °C.	Passed

Test Performed	Applicable Standards	Purpose	Acceptance Criteria	Results
Carrier and Primary Packaging Materials Evaluation	*ISO 11138-1:2017 standard..*	Evaluate the effect of carrier and primary packaging materials of Bionova® BT20 Biological Indicator to confirm that they do not retain or release inhibitory substances and demonstrate their suitability for the intended sterilizations process.	If "no growth" occurs in one or more of the *growth medium controls*, the test procedure shall not be regarded as valid. If "growth" occurs in one or more of the *negative growth controls*, the test procedure shall not be regarded as valid. If "no growth" occurs in one or more of the six *exposed carrier samples*, the carrier shall not be regarded as suitable for the manufacture of inoculated carriers or BIs. If "no growth" occurs in one or more of the three *unexposed carrier samples*, the carrier material shall not be regarded as suitable for the manufacture of inoculated carriers or biological indicators. If "no growth" occurs in one or more of the six *exposed primary packaging samples*, the primary packaging shall not be regarded as suitable for the manufacture of biological indicators. If "no growth" occurs in one or more of the three *unexposed primary packaging samples*, the primary packaging material shall not be regarded as suitable for the manufacture of biological indicators.	Passed
Reduced Incubation Time (RIT) Test	*ISO 11138-1:2017, ISO 11138-8:2021* and the *FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007.*	Validate the 24-hour Reduced Incubation Time for Bionova® BT20 Biological Indicator.	The 24-hour Reduced Incubation Time sensitivity should be greater than or equal to 97 % for each partial sterilization cycle for the three Bionova® BT20 Biological Indicators batches.	Passed
Holding Time Assessment	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007.*	Validate a maximum 7-day holding time between exposure and incubation, during which resistance parameters and spore recovery should remain stable.	Bionova® BT20 Biological Indicators D-value should remain within ± 20 % following the specified holding time. All inoculated samples should show a positive result after 7 days of incubation at 60 °C. Negative controls should show a negative result under the same conditions.	Passed

Test Performed	Applicable Standards	Purpose	Acceptance Criteria	Results
Shelf Life Study	*ISO 11138-1:2017 standard.*	Demonstrate that the specifications of Bionova® BT20 are maintained throughout the labeled shelf life of the product. To achieve this aim, three characteristics should be evaluated: ▪ Spore population stability. ▪ D-value stability. ▪ Product performance.	Spore population stability study In accordance with requirements described in ISO 11138-1:2017, spore population should be accepted when, during the entire shelf-life of the SCBI, it is within the range of 50 to 300 % of the value initially stated by the manufacturer. D-Value stability study According to ISO 11138-1:2017, the D-value shall be acceptable when, during the entire shelf-life of the SCBI, it is within ± 20 % of the value stated by the manufacturer at the time of production. Product performance study Performance of the BI shall not be altered during its shelf-life. The BI shall meet the following parameters: A BI exposed to a successful sterilization process should test negative (culture medium should remain purple) after a 24-hour incubation at 60 °C. A BI used as positive control (not exposed to a sterilization process) or a BI exposed to a non-satisfactory sterilization process, should test positive (culture medium should turn to yellow) after a 24-hour incubation at 60 °C.	Passed
Performance Study for Bionova® BT20 Biological Indicator	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007* and the *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Verify the performance of the device in claimed cycles.	The Biological Indicator should perform as intended in claimed cycles.	Passed

Test Performed	Applicable Standards	Purpose	Acceptance Criteria	Results
Pass/Fail Criteria for Bionova® BT20 chemical indicator label	*ISO 11140-1:2014* and the *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Validate the performance of chemical process indicator on Bionova® BT20 label in resistometer	After exposure to the indicated pass conditions, the chemical indicator should reach its endpoint by turning brown. After exposure to fail conditions, chemical indicator should not reach its endpoint. After exposure to dry heat, no color change or change significantly different from the endpoint condition is expected.	Passed
		Validate the performance of chemical process indicator on Bionova® BT20 label in actual sterilizer	After exposure to pass conditions, the chemical indicator should reach its endpoint by turning brown. After exposure to fail conditions, chemical indicator should not reach its endpoint.	Passed
Endpoint Stability for Bionova® BT20 chemical indicator label	*ISO 11140-1:2014* and the *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Demonstrate the stability of the endpoint reaction of the Chemical Indicator printed on Bionova® BT20 Biological Indicator label at the end of their shelf life and for a period of at least 6 months.	Stability of endpoint reaction of Chemical Indicator printed on Bionova® BT20 Biological Indicator label should be demonstrated at the end of its shelf life and for a period of 6 months.	Passed
Shelf Life Study for Bionova® BT20 chemical indicator label	*FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Provide real-time data to demonstrate that the endpoint response specification of the chemical indicator printed on the Bionova® BT20 Biological Indicator label is maintained over 24 months.	The stability of the endpoint reaction for the chemical indicator printed on the Bionova® BT20 Biological Indicator label should be demonstrated throughout its shelf life when stored under the labeled storage conditions.	Passed
Biocompatibility for Bionova® BT20 chemical indicator label	*ISO 11140-1:2014* and the *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Demonstrate that Bionova® BT20 Chemical Indicators label do not offset or transfer when is in contact with the same substrate from which they were manufactured.	The chemical indicator printed on the Bionova® BT20 Biological Indicator should not release any substance or bleed when they come in contact with their substrate and are subject to the sterilization process.	Passed

7. Clinical Comparison to the Predicate Device

Clinical testing was not required for this submission.

8. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device, the Terragene® Bionova® BT20 Biological Indicator, is as safe, as effective, and performs as well as the legally marketed predicate device, the Terragene® Bionova® BT220 SCBI cleared per K163646, Class II (21 CFR 880.2800), product code FRC.