December 12, 2024

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

Re: K242453
Trade/Device Name: Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2);Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C)
Regulation Number: 21 CFR 880.2806
Regulation Name: Biological sterilization indicator with indirect growth detection
Regulatory Class: Class II
Product Code: FRC
Dated: November 13, 2024
Received: November 13, 2024

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,

PAULO LARANJEIRA -S

Digitally signed by PAULO LARANJEIRA -S
Date: 2024.12.12 10:22:58 -05'00'

for: Christopher Dugard
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.

Submission Number *(if known)*

K242453

Device Name

Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2);
Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C)

Indications for Use *(Describe)*

Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The device is intended for routine monitoring of the following steam sterilization processes:

• 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
132 °C, 4 minutes
135 °C, 3 minutes

Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The device is intended for routine monitoring of the following steam sterilization processes:

• 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
132 °C, 4 minutes
135 °C, 3 minutes

Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60°C and reads the Terragene® Bionova® Photon Biological Indicator (BT225) which is a 7-second readout Self-Contained Biological Indicator (SCBI) inoculated with a minimum of 10^6 viable Geobacillus stearothermophilus bacterial spores.

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.

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510(k) Summary
for
Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2); Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C)
K242453

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: hernando.carrizo@terragene.com

Date of Summary: 11 December 2024

1. **Device Name and Classification:**

Common or Usual Name:	Biological Indicator (BI) Challenge Pack
Proprietary Name:	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2); Terragene® Bionova® Photon Process Challenge Device with moving- front integrator (PCD225-C)
Classification Name:	Indicator, Biological Sterilization Process
Device Classification:	Class II, 21 CFR 880.2800
Product Code:	FRC

2. Predicate Device:

Terragene Bionova® PCD (PCD224-2); Terragene Bionova® PCD (PCD224-C), K191021

3. Description of Device:

Bionova® Photon Process Challenge Devices consist of a disposable pre-assembled package as outlined in ANSI/AAMI ST79:2017 which contain a Bionova® Photon Biological Indicator (BT225), a Record Card and a chemical integrator that gives instant visible indication that sterilizing conditions have been reached. Each Bionova® Photon PCD consists of a stack of porous cards holding a Self-Contained Biological Indicator (SCBI) that contains a population of *Geobacillus stearothermophilus* ATCC®7953 spores on a carrier as well as growth indicator medium contained in a glass ampoule. Each SCBI has a process indicator on the label that changes from pink to brown when exposed to steam. These PCDs present a challenge to the sterilization process equivalent to the 16-towel process challenge device (PCD) recommended by the Associate for the Advancement of Medical Instrumentation (AAMI).

4. Indications for Use

Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The device is intended for routine monitoring of the following steam sterilization processes:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal	132°C	4 minutes
Dynamic-air-removal	135°C	3 minutes
Gravity-displacement	132°C	25, 15, and 10 minutes
Gravity-displacement	135°C	10 minutes

Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The device is intended for routine monitoring of the following steam sterilization processes:

Cycle Type	Exposure Temperature	Exposure Time
Dynamic-air-removal	132°C	4 minutes
Dynamic-air-removal	135°C	3 minutes
Gravity-displacement	132°C	25, 15, and 10 minutes
Gravity-displacement	135°C	10 minutes

Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60°C and reads the Terragene® Bionova® Photon Biological Indicator (BT225) which is a 7-second readout Self-Contained Biological Indicator (SCBI) inoculated with a minimum of 10^6 viable *Geobacillus stearothermophilus* bacterial spores.

5. Comparison of Technological Characteristics with the Predicate Device

Both the submission and predicate challenge packs are designed to increase resistance beyond that measured with a standalone BI and both represent a challenge to the sterilization process equivalent to the AAMI reference PCD. The subject and predicate devices have the same intended use. The only difference between the Indication for Use statements is that the subject devices add the indication that they are to be used in conjunction with Terragene® Bionova® Photon Auto-reader incubator.

The differences in technological characteristics between the submission and predicate challenge pack are illustrated in the Device Comparison Table (**Table 1**).

Table 1: Device Comparison Table

Feature	Subject Devices: (K242453)	Predicate Devices: (K191021)	Comparison
Intended Use	Single Use biological indicator process challenge device	Single Use biological indicator process challenge device	Identical

Feature	Subject Devices: (K242453)	Predicate Devices: (K191021)	Comparison
Indications for Use	Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2) and Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C) provide a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The devices are intended for routine monitoring of the following steam sterilization processes: Dynamic-air-removal 132°C 4 minutes Dynamic-air-removal 135°C 3 minutes Gravity-displacement 132°C 25, 15, and 10 minutes Gravity-displacement 135°C 10 minutes Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60°C and reads the Terragene® Bionova® Photon Biological Indicator (BT225) which is a 7-second readout Self-Contained Biological Indicator (SCBI) inoculated with a minimum of 10^6 viable *Geobacillus stearothermophilus* bacterial spores.	Terragene Bionova® PCD (PCD224-C, PCD224-2) provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring and sterilizer qualification testing steam sterilization processes. Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60° C and 37° C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.	Similar. The differences between the Indications for Use include: the subject devices are not intended to be used for qualification and are to be used in conjunction with the Terragene® Bionova® Photon Auto-reader Incubator.

Feature	Subject Devices: (K242453)	Predicate Devices: (K191021)	Comparison
General design	Porous cards holding a Self-contained Biological Indicator and a Chemical Integrator (Type 5) according to ISO 11140-1: 2014). The system also contains a Self-adhesive record card where sterilization cycle may be written and is contained in a cardboard box with a Process Indicator (Type 1) according to ISO 11140-1: 2014).	Porous cards holding a Self-contained Biological Indicator and a Chemical Integrator (Type 5) according to ISO 11140-1: 2014). The system also contains a Self-adhesive record card where sterilization cycle may be written and is contained in a cardboard box with a Process Indicator (Type 1) according to ISO 11140-1: 2014).	Identical
Biological indicator	Terragene® Bionova® Photon Biological Indicator (BT225) 10^6 *Geobacillus stearothermophilus* spores	Terragene® Bionova® SCBI (BT224) 10^6 *Geobacillus stearothermophilus* spores	Different. The subject device contains a different biological indicator with indirect growth detection.
Biological Indicator Incubation temperature	60 ± 2°C	60 ± 2°C	Identical
Biological Indicator Readout time	7-second final fluorescent result in Terragene® Bionova® Photon Auto-reader Incubator (BPH)	20-minute fluorescent result in Bionova® Auto-reader Incubator	Different. The subject device has a shorter readout time in a different incubator.

Feature	Subject Devices: (K242453)	Predicate Devices: (K191021)	Comparison
Biological Indicator Mechanism of Action	Upon the SCBI activation (the ampoule contained in the SCBI is crushed), the culture medium soaks the carrier and ANS comes into contact with the spores (and their outer proteins). In non-sterilized SCBIs or after unsuccessfully sterilization processes, the ANS molecules bind to the hydrophobic cavities in structurally intact spore-associated proteins, significantly increasing its fluorescence signal, detected by the Auto-reader. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure. Optionally, a visual color change confirmation can be performed.	In those SCBIs exposed to an inefficient sterilization cycle, the active α-glucosidase enzymes, which are naturally located in different regions of the *Geobacillus stearothermophilus* spore structure, catalyze the breakdown of the non-fluorescent α-MUG substrate, releasing a fluorescent by-product, detected by the Auto-reader. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure. Optionally, a visual color change confirmation can be performed.	Different. The subject device contains a biological indicator with a different fluorophore. The fluorescence readout does not depend on an enzymatic reaction.
Biological Indicator Resistance Characteristics	D-value$_{132\ ^{o}C} \geq 10$ secs Z-value$_{132\ ^{o}C} \geq 10$ ºC Survival Time$_{132\ ^{o}C}$ [($\log_{10}$ nominal population - 2) x D-value$_{132\ ^{o}C}$] ≥ 1 min D-value$_{135\ ^{o}C} \geq 8$ secs Z-value$_{135\ ^{o}C} \geq 10$ ºC Survival Time$_{135\ ^{o}C}$ [($\log_{10}$ nominal population - 2) x D-value$_{135\ ^{o}C}$] ≥ 40 secs	D-value$_{132\ ^{o}C} \geq 10$ secs Z-value$_{132\ ^{o}C} \geq 10$ ºC Survival Time$_{132\ ^{o}C}$ [($\log_{10}$ nominal population - 2) x D-value$_{132\ ^{o}C}$] ≥ 1 min D-value$_{135\ ^{o}C} \geq 8$ secs Z-value$_{135\ ^{o}C} \geq 10$ ºC Survival Time$_{135\ ^{o}C}$ [($\log_{10}$ nominal population - 2) x D-value$_{135\ ^{o}C}$] ≥ 40 secs	Identical
Chemical Integrator	Integron® IT26-C chemical integrator (PCD225-C) Bionova® PCDBl-2-RC Chemical integrator (PCD225-2)	Integron® IT26-C chemical integrator (PCD224-C) Bionova® PCDBl-2-RC Chemical integrator (PCD224-2)	Identical
Chemical Integrator Endpoint Specifications (Minimum Stated Values)	121°C: 16.5 minutes 132°C: 2.0 minutes 135°C: 1.2 minutes	121°C: 16.5 minutes 132°C: 2.0 minutes 135°C: 1.2 minutes	Identical

Feature	Subject Devices: (K242453)	Predicate Devices: (K191021)	Comparison
Chemical Integrator Color Change	Integron® IT26-C chemical integrator (PCD225-C): The extent of migration of the dark bar along the ACCEPT/REJECT zone indicates whether sterilization conditions were met or not. Bionova® PCDBl-2-RC Chemical integrator (PCD225-2): turns from purple to green when sterilization conditions were met.	Integron® IT26-C chemical integrator (PCD224-C): The extent of migration of the dark bar along the ACCEPT/REJECT zone indicates whether sterilization conditions were met or not. Bionova® PCDBl-2-RC Chemical integrator (PCD224-2): turns from purple to green when sterilization conditions were met.	Identical
Mechanism to distinguish processed and unprocessed challenge pack	External Chemical Process Indicator that turns from light blue to dark grey/black upon steam exposure	External Chemical Process Indicator that turns from light blue to dark grey/black upon steam exposure	Identical
Resistance Comparison to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Equivalent in resistance to the AAMI ST79 16 Towel PCD	Identical
Shelf life	18 months	24 months	Different. The subject device has a shorter shelf life.
Accessories	Terragene® Bionova® Photon Auto-reader Incubator (BPH)	Bionova® Auto-reader Incubator	Different. The subject device has a different incubator.

6. Nonclinical Comparison to the Predicate Device

The differences between the submission and predicate device have been evaluated through performance tests for the Terragene® Bionova® Photon Process Challenge Device with unique-point integrator (PCD225-2); Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).

Performance of the Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2); Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C) were verified through the following tests:

Test Performed	Device Description	Applicable Standards	Purpose	Acceptance Criteria	Results
Performance study comparison of Bionova® Photon Process Challenge Devices to the standalone biological and integrator indicators	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2) and Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007* and *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Demonstrate that the Bionova® Photon Process Challenge Devices provide a greater challenge to the steam sterilization process than the SCBI and chemical integrator themselves.	Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) provide a greater challenge than the Bionova® Photon BT225 SCBI and Bionova® PCDBI-2-RC /Integron® IT26-C chemical integrator themselves.	Passed
Performance study comparison of Bionova® Photon Process Challenge Devices to the AAMI 16-Towel Test Pack	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2) and Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007* and ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*	Demonstrate that the performance of Bionova® Photon Process Challenge Devices is comparable to the performance of the user-assembled test pack described in ANSI/AAMI ST79:2017.	The response of Bionova® Photon BT225 SCBI and Bionova® PCDBI-2-RC /Integron® IT26-C chemical integrators inside the Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) should be equivalent to the performance of the same indicators in the 16-towel ANSI/AAMI ST79:2017 user-assembled test pack for steam sterilization processes.	Passed
Performance study of the chemical integrators in the Bionova® Photon Process Challenge Devices	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2) and Terragene®	*FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators,*	Compare the performance of the Bionova® PCDBI-2-RC /Integron® IT26-C chemical integrators	Chemical integrators within the Bionova® Photon PCD should show pass results under passing	Passed

compared to AAMI reference biological indicator test packs	Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).	*December 19, 2003.*	within the Bionova® Photon Process Challenge Devices to the Bionova® Photon BT225 Biological Indicator inside the AAMI standard test packs.	conditions while under failing conditions, the chemical integrators should show fail results. These results should be consistent with the outcome of the Bionova® Photon BT225 Biological Indicator within the standard test packs.	
Performance study comparison of Bionova® Photon Process Challenge Devices to the predicate devices in claimed cycles	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2) and Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007* and *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Compare the performance of the Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) to the predicate devices (PCD224-2 and PCD224-C) in claimed cycles (complete and incomplete cycles).	Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) should demonstrate equivalent performance to the Bionova® PCD224-2 and PCD224-C.	Passed
Performance Study for Bionova® Photon Process Challenge Devices in claimed cycles	Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2) and Terragene® Bionova® Photon Process Challenge Device with moving-front integrator (PCD225-C).	*FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007* and *FDA Guidance for Industry and FDA Staff on Premarket Notification [510(k)] Submissions for Chemical Indicators, December 19, 2003.*	Verify the performance of the Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) in claimed sterilization cycles, both for complete cycles (PASS CONDITION) and for incomplete cycles (FAIL CONDITION).	Bionova® Photon Process Challenge Devices (PCD225-2 and PCD225-C) perform as intended in claimed cycles.	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 submission device, the Terragene® Bionova® Photon Process Challenge Device with unique- point integrator (PCD225-2); Terragene® Bionova® Photon Process Challenge Device with moving- front integrator (PCD225-C), are as safe and as effective as the legally marketed predicate device, Terragene Bionova® PCD (PCD224-C, PCD224-2) cleared per K191021, Class II (21 CFR 880.2800), product code FRC.