October 22, 2021

Plasmapp Co., Ltd.
℅ Candace Cederman
Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K212193
Trade/Device Name: Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC, JOJ
Dated: September 20, 2021
Received: September 21, 2021

Dear Candace Cederman:

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, PhD
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)*
K212193

Device Name
Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), Terragene Cintape® (CT40)

Indications for Use *(Describe)*
Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

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.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.

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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1. General Information

Applicant/Submitter:	Plasmapp Co., Ltd. BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon, 34141, Rep. of Korea (South Korea) Tel: +82 (0)42 716 2115
Contact Person:	Candace Cederman
Address:	CardioMed Device Consultants LLC 3168 Braverton Street Suite 200 Edgewater, MD 21037 Tel: +1 410 674 2060
Preparation Date:	October 7, 2021

2. Device Name and Code

Device Trade Name:	Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)
Common Name:	Self-Contained Biological Indicator, Self-Contained Biological Indicator Incubator, Chemical Indicator
Classification Name:	Sterilization Process Indicator
Product Code:	FRC, JOJ
Regulation Number:	21 CFR 880.2800
Classification:	Class II
Review Panel:	General Hospital

3. Device Description

Terragene® Bionova® BT96 Fluorescence Super Rapid Readout Biological Indicators are single-use Self-Contained Biological Indicators (SCBIs) that consist of a polypropylene tube, a spore carrier, and a glass ampoule with a culture medium, enclosed with a colored cap. Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a spore carrier, a plastic cap with holes and a barrier permeable to Plasma or Vaporized Hydrogen Peroxide. Each BT96 has a Process Indicator on label that changes from purple to green when exposed to hydrogen peroxide. The Bionova® BT96 Biological Indicators have been designed for monitoring of Vaporized Hydrogen Peroxide sterilization processes when used in conjunction with Bionova® IC10/20FR, IC10/20FRLCD or MiniBio Auto-Readers Incubators.

Chemdye® CD42 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of plastic strips printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes within loads, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.

Cintape® CT40 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of a roll of self-adhesive plastic tape printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.
The adhesive component of the tape allows the adhesion to different types of packaging and wraps, such as cloth, paper and plastic.

4. Indications for Use / Intended Use

The revised indications for use are as follows:

> Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.
>
> 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.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.

5. Technical Characteristics in Comparison to Predicate Devices

The subject device uses identical technology as the cited predicate devices and has the same intended uses. Based upon the overall performance characteristics for the sterilization process indicators used with the STERLINK™ sterilizer, Plasmapp Co., Ltd. believes that there are no significant differences in usage for the underlying technological principles between the subject devices and predicate devices.

	Subject Device	**Predicate Device**
Sponsor	Plasmapp Co., Ltd.	Terragene® S.A.
Device Name	Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)	Same
510(k) Number	K212193	K191021
Manufacturer	Terragene® S.A.	Same
Device Classification Name	Sterilization Process Indicator	Same
Classification Product Code	FRC (biological indicators) JOJ (chemical indicators)	Same
Regulation Number	21 CFR 880.2800	Same

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Sponsor</td><td>Plasmapp Co., Ltd.</td><td>Terragene® S.A.</td></tr>
<tr><td>Indications for Use</td><td>Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC.
Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.
Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.</td><td>Excerpted from K191021:
Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC.
Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD40, CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from purple to green for CD40 and red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.</td></tr>
<tr><td>Intended Use: Cycles</td><td><table><tr><td colspan="2">Vaporized Hydrogen Peroxide</td></tr><tr><td>Models</td><td>Cycle</td></tr><tr><td>BT96, CD42, CT40</td><td>STERLINK™ FPS-15s Plus - Chamber mode</td></tr></table></td><td><table><tr><td colspan="2">Vaporized Hydrogen Peroxide</td></tr><tr><td>Models</td><td>Cycles</td></tr><tr><td rowspan="3">BT96, CD42, CT40</td><td>STERRAD 100S (54 minutes)</td></tr><tr><td>STERRAD Standard and Express Cycles</td></tr><tr><td>V-Pro Max and Sterizone VP4</td></tr></table></td></tr>
<tr><td colspan="3">Terragene Bionova® SCBI (BT96)</td></tr>
<tr><td>Type of Biological Indicator</td><td>Self-Contained</td><td>Same</td></tr>
<tr><td>Organism Spore, Species, Strain</td><td>Geobacillus stearothermophilus ATCC 7953 spores inoculated on a strip (spore carrier)</td><td>Same</td></tr>
<tr><td>Viable Spore Population</td><td>$\geq 10^6$</td><td>Same</td></tr>
<tr><td>Resistance characteristics</td><td>D-value
Survival time/Kill window</td><td>Same</td></tr>
</table>

	Subject Device	**Predicate Device**
Sponsor	Plasmapp Co., Ltd.	Terragene® S.A.
Intended Sterilization Cycles	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)	STERRAD® 100S (54-minute Short cycle, 72-minute Long cycle), STERRAD® 100NX (Standard Cycle – 47 minutes, Express Cycle - 24 minutes), V-Pro® maX (Non Lumen Cycle - 28 minutes, Flexible Cycle – 35 minutes, Lumen Cycle - 55 minutes), Sterizone® VP4 (Cycle 1)
Shelf Life	2 years	Same
Terragene Chemdye® (CD42), Terragene Chemdye® (CT40)		
Intended Sterilization Cycles	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)	STERRAD® 100S sterilization cycles: • 54-minute Short cycle for most surgical instruments • 72-minute Long cycle for flexible endoscopes and instruments with longer lumen STERRAD® 100NX® sterilization cycles: • 24-minute express cycle for fast turnaround endoscopes and many other instruments • 47-minute standard cycle for most surgical instruments AMSCO® V-PRO maX cycles: • 28-minute non-lumen cycle for most surgical instruments • 35-minute flexible cycle for single or dual channel flexible endoscopes and any non-lumen devices • 55-minute lumen cycle for stainless steel lumen instruments with a single, dual or triple channel. Sterizone VP4 cycle.
Device design	Strip, Tape	Same
Color Change upon Exposure to H_2O_2	CD42: red to yellow CT40: purple to green	Same
Recommended Storage Conditions	Dry place, away from sunlight, at temperature between 10-30ºC, 30-80% relative humidity. Do not wet. Do not store close to sterilizing agents.	Same
Shelf Life	5 years	Same
The subject and predicate devices are identical with respect to the organism, accessories, spore population, resistance characteristics, culture conditions, carrier materials, packaging, storage conditions and claimed shelf life. The only difference between the subject and predicate devices are the proposed indications for use, to label the indicators for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.		

6. Performance Data

Non-clinical tests were performed using following standards:

Item	Test	Standard/Guidance Document	Result
Self-Contained Biological Indicator	Viable spore population assay	ANSI/AAMI/ISO 11138-1:2017	Pass
	Resistance characteristics study	ANSI/AAMI/ISO 11138-1:2017	Pass
	Carrier and primary packaging materials evaluation	ANSI/AAMI/ISO 11138-1:2017	Pass
(BT96)	Holding time assessment	Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions	Pass
	Reduced incubation time validation test	Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions	Pass
	Recovery protocols: Recovery medium test	ANSI/AAMI/ISO 11138-1:2017	Pass
	Visual readout stability: Visual inspection test	ANSI/AAMI/ISO 11138-1:2017	Pass
	Shelf life study	ANSI/AAMI/ISO 11138-1:2017	2 years
	Resistance Validation for Biological Indicator	ISO 11138-1:2017	Pass
	BI & Test Pack Validation	Guidance for Industry and FDA Staff- Biological Indicator (BI) Premarket Notification [510(k)] Submissions	Pass
Chemical Indicator (CD42, CT40)	Performance characteristics obtained from resistometer	Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Chemical Indicators ANSI/AAMI/ISO 11140-1:2014	Pass
	Biocompatibility	Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Chemical Indicators ANSI/AAMI/ISO 11140-1:2014	Pass
	Endpoint stability	ANSI/AAMI/ISO 11140-1:2014	Pass
	Shelf life study	Premarket Notification [510(k)] Submissions for Chemical Indicators	5 years
	Chemical Indicator Validation	ANSI/AAMI/ISO 11140-1:2014	Pass

7. Conclusions

The conclusions drawn from the non-clinical tests demonstrates that the device in 510(k) submission K212193, Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40) are as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K191021.