DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 7, 2017

GKE-GMBH
Ulrich Kaiser, Ph.D.
General Manager
Auf Der Lind 10
Waldems, 65529 DE

Re: K163144
Trade/Device Name: Gke Steri-Record Steam Mini-Bio-Plus Self-Contained Biological Indicator (SCBI)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: March 1, 2017
Received: March 6, 2017

Dear Dr. Kaiser:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K163144

Device Name

gke Steri-Record Steam Mini-Bio-Plus self-contained biological indicator (SCBI)

Indications for Use *(Describe)*

The gke Steam SCBI is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of nominal 100,000 spores of Geobacillus stearothermophilus on a carrier and enclosed in a protective plastic vial. The spores have a known resistance to certain steam sterilization cycles. The device can be used for gravity and pre-vacuum cycles according to the following conditions: 121 °C, 30 minutes / 132, 134 and 135°C, 3 minutes.
Subsequent growth or failure of the microorganisms after an incubation time of 24 hours at 55-60 °C indicates the adequacy of sterilization.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary for *gke Steri-Record* Steam Mini-Bio-Plus self-contained biological indicator (SCBI)

K163144

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Prepared on: April 05, 2017

Device Name: ***gke*** *Steri-Record* Steam Mini-Bio-Plus self-contained biological indicator (SCBI)

Classification: Class II Medical Device, FDA Product Code FRC, General Hospital

Predicate Devices: Legally Marketed) 3M™ Attest™ 1262/1262P (pre-amendment)

Intended Use: The ***gke*** Steam SCBI is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization. The device consists of nominal 100,000 spores of Geobacillus stearothermophilus on a carrier and enclosed in a protective plastic vial. The spores have a known resistance to certain steam sterilization cycles. The device can be used for gravity and pre-vacuum cycles according to the following conditions:

121 °C, 30 minutes / 132, 134 and 135°C, 3 minutes. Subsequent growth or failure of the microorganisms after an incubation time of 24 hours at 55-60 °C indicates the adequacy of sterilization.

Description of Device:

The ***gke*** Steri-Record Steam Mini-Bio-Plus SCBI uses a plastic vial with a minimized internal volume containing a biological indicator spore disc and a glass ampoule with a growth medium and pH-indicator inside. The growth medium is optimized to support growth.

Operational Principles:

The ***gke*** Steri-Record Steam Mini-Bio-Plus SCBI is placed in the most difficult to sterilize area of a load. Upon cycle completion, the SCBI is removed and activated by crushing the growth medium ampoule to immerse the disc in the growth medium. The activated SCBI should be incubated at 55-60 °C. The SCBI should be monitored for visible signs of growth. Growth will be indicated by a color shift from purple to yellow. The absence of growth indicates the exposure was effective.

Statement of Similarity to Legally Marketed Predicate Device:

The gke Steri-Record Steam Mini-Bio-Plus Self-Contained Biological Indicators have the following similarities to the legally marketed predicate device:

- Incorporation of the same or similar materials
- Similar intended use
- Have the same or similar shelf life, and
- The same or similar materials for packaging

In summary, the data provided demonstrates substantial equivalence to the predicate device.

A device comparison table is provided below.

Element	New Device	Predicate Device
	gke Steam SCBI	3M™ Attest™
product type	Self-contained biological indicator	Self-contained biological indicator
Intended use	Steam at 121°C, 132°C, 134°, 135°C	Steam at 121°C and 132°C
Construction	Vial, cap, paper cap liner, paper spore disc, glass ampoule of growth media	Vial, cap, paper cap liner, paper spore disc, glass ampoule of growth media

	modified with pH indicator	modified with pH indicator
Activation	Squeeze to break ampoule	Squeeze to break ampoule
Organism	Geobacillus stearo-thermophilus ATCC® 7953 or other micro-organism of demonstrated equivalent performance as required by ISO 11138-3	Geobacillus stearothermophilus ATCC® 7953
Viable spore population	$>10^5$/unit per ISO 11138	10^5/unit
Certified resistance D-value at 121°C	1.5-3.0 min	1.5-3.0 min
z-value	≥6°C per ISO 11138	≥6°C per ISO 11138
Survival/kill window	Survival time: ≥4.5 min Kill time: ≥13.5 min. both at 121 °C per ISO 11138-3	Per USP and ISO 11138
Incubation temperature	55°C-60°C	56°±2°C
Readout time	24 h	12 hours-48h final detection
Media color (Initial))	Purple	Purple
Media color(Growth)	Yellow	Yellow
Shelf Life	24 Month	18 Month

There are no relevant deviations between the gke Steam SCBI and the predicate device.

Non relevant deviations:
The incubation temperature of the gke Steam SCBI is 55 to 60 °C, the predicate device requests 54 to 58 °C (56°±2°C). It is a non-relevant deviation to the incubation temperature of the predicate device.
The predicate device has a readout time of 12 hours to 48 hours for final detection. gke Steam SCBI has a readout time of 24 hours as seen in the reduced incubation time report. The readout times of both products are in a similar range. Therefore, it is a non-relevant deviation.

Additionally, to the shelf life of the whole complete device gke describes the shelf life of the components of gke Steam SCBI, too. In summary, the gke Steam SCBI and the predicate device

have the same shelf of 18 months. No relevant deviation.

Description of Testing:

Per FDA recognized consensus standards and guidance documents (Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions, issued on October 4, 2007) testing was performed for steam sterilization processes using multiple lots of gke Steri-Record Steam Mini-Bio-Plus self-contained biological indicators over the range of the shelf life:

All population and performance parameters were measured in conformity with FDA recognized consensus standards:

- USP Biological Indicator for Steam Sterilization, Self-Contained
- ANSI/AAMI/ISO 11138-1: 2006 Sterilization of health care products – Biological indicators – Part 1: General Requirements
- Guidance for Industry and FDA Stuff (BI) Premarket Notification [510(k)] Submissions, issued on October 4, 2007)

Summary of testing

Test	Description	Acceptance Criteria	Result
Total Viable Spore Count	According USP (55) and ISO 11138	≥10^5/unit per ISO 11138-3	Passed
D value	ISO 11138-1	≥1.5 min. at 121°C per ISO 11138-3	Passed
z-value	ISO 11138-1	≥6°C per ISO 11138-3	Passed
Survival/Kill Windows	ISO 11138-1:2006	Survival time: ≥4.5 min Kill time: ≥13.5 min. both at 121°C per ISO 11138-3	Passed
Carrier and Primary Packaging Materials Evaluation	ISO 11138-1:2006, 5.2 and Annex B and ISO 11138-3:2006	No inhibitory properties on the growth of gke Steam SCBI after exposure to steam sterilization processes ISO 11138-1:2006, 5.2 and Annex B	Passed
Holding Time Assessment	FDA Guidance “Biological Indicator (BI) Premarket Notification (510(k)) Submissions”	No negative impact on the growth of SCBIs after ≤ 72 h holding time.	Passed

	Attachment II)		
Reduced Incubation Time Studies	FDA Guidance "Biological Indicator (BI) Premarket Notification [510(k)] Submissions" Attachment II	30 – 80% of BIs survived in all tested partial cycles. No further growth of BIs after 24 hours of incubation is observed.	Passed
Medium Suitability	USP medium suitability for Self-Contained Biological Indicators (SCBIs)	USP medium suitability for Self-Contained Biological Indicators (SCBIs)	Passed

Conclusion of performance testing - bench
Based on the results of the performance testing study the gke Steam SCBI correspond to the following standards, which are also our acceptance criteria:

- USP Biological Indicator for Steam Sterilization, Self-Contained
- ANSI/AAMI/ISO 11138-1: 2006 Sterilization of health care products – Biological indicators – Part 1: General Requirements
- Guidance for Industry and FDA Stuff (BI) Premarket Notification [510(k)] Submissions, issued on October 4, 2007)

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device.