



Food and Drug Administration
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February 26, 2016

BCR Diagnostics, Inc.
Boris Rotman, Ph.D.
Vice President, CSO
145 S. 79th Street – Ste. 12
Chandler, AZ 85226

Re: K151482

Trade/Device Name: BCR-30-min BI™ and RBIP-ST30™ Readout Accessory
Regulation Number: 21 CFR 880.2800
Regulation Name: Chemical/Physical Sterilization Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 27, 2016
Received: February 1, 2016

Dear Dr. Rotman:

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" (21CFR 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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A.6 Statement of Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
K151482

Device Name

BCR-30-min BI™ and RBIP-ST30™ Readout Accessory

Indications for Use (Describe)

Use the BCR-30-min BI™ and the RBIP-ST30™ together for monitoring performance of gravity displacement steam sterilization cycles of 30 minutes at 250°F (121°C). The BCR-30-min BI™ in conjunction with the RBIP-ST30™ provides final fluorescence results in 30 minutes.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Pre-market Notification Summary

K151482

Sponsor Information:

BCR Diagnostics, Inc.
145 S. 79th Street – Ste. 12
Chandler, AZ 85226

Contact Person: Boris Rotman, Ph.D., CSO.
Phone Number: (480) 809-6156
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email: bcr@bcr.necoxmail.com
Date of Summary: February 25, 2016

Device Name and Classification:

Common or Usual Name: Biological Indicator
Biological Indicator Readout Accessory
Trade/Proprietary Name: BCR-30-min BITM and RBIP-ST30TM Readout Accessory
Classification Name: Chemical/Physical Sterilization Indicator
Regulation Number: 21 CFR 880.2800
Regulatory Class: Class II
Product Code: FRC

Predicate Devices:

- ‘Intended Use Predicate’ for BCR-30-min BITM: 3M AttestTM 1292 Rapid Readout Biological Indicator for Steam, K090569.
- ‘Readout Predicate’ for RBIP-ST30TM: 3M Attest 490 Auto-reader, K103277.

Description of Device:

BCR-30-min BITM

The BCR-30-min BITM is designed to be used with its readout accessory, the RBIP-ST30TM robotic processor, for validating and challenging performance of gravity displacement steam sterilization cycles at 250°F (121°C).

The BCR-30-min BITM consists of a strip (6.0 x 60 mm) of filter paper (Whatman GF/A) inoculated in the center with about 10⁶ living spores of *Geobacillus stearothermophilus* ATCC No. 7953. The strip is packaged in a #30 blue glassine pouch (1 x 3 inch). The BCR-30-min BITM should be placed in the center of the load or in the most difficult to sterilize area.

RBIP-ST30™ Readout Accessory

In the RBIP-ST30™, the spores of the BCR-30-min BI™ are first converted into F-spores™ and then they are incubated for 30 min at 55±2°C to allow germination of living F-spores™. The device utilizes the fact that F-spores™ are not fluorescent *per se* but produce intense fluorescence when germinated. Accordingly, the RBIP-ST30™ detects failure of a steam sterilization cycle when significant fluorescence is present.

The RBIP-ST30™ is designed to automatically process the BCR-30-min BI™ to obtain a fluorescence reading within 30 minutes. The fluorescence results at 30 minutes meet the FDA's requirement of > 97% alignment with the result after the conventional incubation time of 7 days.

Indications for Use:

Use the BCR-30-min BI™ and the RBIP-ST30™ together for monitoring performance of gravity displacement steam sterilization cycles of 30 minutes at 250°F (121°C). The BCR-30-min BI™ in conjunction with the RBIP-ST30™ provides final fluorescence results in 30 minutes.

Substantial Equivalence of BCR-30-min BI™ to “Intended Use” Predicate Device 3M Attest™ 1292 Rapid Readout Biological Indicator (K090569):

Performance of the BCR-30-min BI™ was determined using three (3) separate spore lots from independent spore cultures. A Summary of the Nonclinical Testing is shown in the table below.

Summary of a Comparative Validation of the BCR-30-min BI™

DEVICE CHARACTERISTICS	“INTENDED USE PREDICATE” 3M Attest™ 1292 BI, K090569	NEW DEVICE BCR-30-min BI™
Intended use • Method of sterilization	Gravity displacement steam	Gravity displacement steam
Indications for Use	Use the 3M Attest 1292 RRBI and the 3M Attest 490 Auto-reader together for monitoring: 1. Performance of gravity displacement steam sterilization cycles of 30 minutes at 250°F (121°C). 2. Performance of vacuum assisted steam sterilization cycles at 270°F (132°C). The 3M Attest 1292 RRBI in conjunction with the 3M Attest 490 Auto-reader provide final fluorescence results in 180 minutes.	Use the BCR-30-min BI™ and the RBIP-ST30™ together for monitoring: 1. Performance of gravity displacement steam sterilization cycles of 30 minutes at 250°F (121°C). The BCR-30-min BI™ in conjunction with the RBIP-ST30™ provide final fluorescence results in 30 minutes.
Organism • Spores, Species, Strain	<i>Geobacillus stearothermophilus</i> from ATCC™ 7953	<i>Geobacillus stearothermophilus</i> from ATCC™ 7953
Viable spore population	About 10 ⁶ spores	About 10 ⁶ spores
Carrier Material	Polyethylene terephthalate paper	Glass fiber paper

Resistance Characteristics*		
• D-Value	1.5-2.2 min	1.9 min
• Z-Value	10-13 °C	15.5 °C
• Survival Time	7-10 min	7.9 min
• Kill Time	16-23 min	19 min
Incubation Temperature	60°C	55±2 °C
Reduced Incubation Time (>97% correlation to the 7-day visual readout result)	Fluorescence result in 180 min	Fluorescence result in 30 min
Shelf-life	2 years	Six months

*Resistance values for the predicate were obtained from the 3M Attest™ 1292 brochure.

Testing of the BCR-30-min BI™ summarized above was conducted following the FDA guidance and standards below:

- FDA's Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification 510(k) Submissions; October 4, 2007.
- ANSI/AAMI/ISO 11138-1:2006/(R) 2010 Sterilization of health care products – Biological indicators - Part 1: General Requirements.
- ANSI/AAMI/ISO 11138-3:2006/(R) 2010 Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
- United States Pharmacopeia, Chapter <1035> Biological Indicators for Sterilization and Chapter <55> Biological Indicators - Resistance Performance Tests.

The results of these tests show that the BCR-30-min BI™, when used with the RBIP-ST30™, complies with ANSI/AAMI/ISO 11138-1:2006/(R) 2010 and ANSI/AAMI/ISO 11138-3:2006/(R) 2010, the USP requirements for biological indicators, as well as the FDA's Guidance for Biological Indicators.

Substantial Equivalence of RBIP-ST30™ to “Readout Predicate” Device 3M Attest 490 Auto-reader:

Since the RBIP-ST30™ is a required readout accessory of the BCR-30-min BI™, the performance of the RBIP-ST30™ was determined at each step during the validation of the BCR-30-min BI™. The table below shows the functionality and characteristics of the new device compared to the predicate.

DEVICE CHARACTERISTICS	“READOUT PREDICATE” 3M Attest 490 Auto-reader (K103277)	NEW DEVICE RBIP-ST30™
Intended use	The 3M Attest 490 Auto-reader is designed to incubate and automatically read the 3M Attest™ 1492 BI for a final fluorescent result at 30 min.	The RBIP-ST30™ readout accessory is designed to incubate and automatically read the BCR-30-min BI™ for a final fluorescent result at 30 min.
Incubation Temperature	56±2 °C	55±2 °C

Basis of Rapid Readout	Fluorescence of BI medium	Fluorescence of F-spores™
Method of Fluorescence Detection	UV LED, optical filters, sensing by photodiode	Blue LED, optical filters, detection, sensing by CCD array
Indicator of Adequate Sterilization Cycle	(-) on LCD Display.	Fluorescence below cut-off value
Indicator of Possible Sterilization Cycle Failure	(+) on LCD Display. Audible Alarm	Fluorescence above cut-off value
Incubation wells	10—reader/incubation wells	10—cartridge wells
Voltage Range	100-240 Volts AC	110 Volts
Product Safety	UL/IEC 61010-1	EN 61326-1
EMC Compliance	FCC Part 15, Subpart B, Class A	FCC Part 15, Subpart B, Class A

Statement of Substantial Equivalence:

The RBIP-ST30™ was tested for safety by a certified Testing Laboratory to demonstrate compliance to EN 61326-1. All tests were conducted using measurement procedure from CISPR 16 as appropriate.

Based on the same intended use and similar performance data, the BCR-30-min BI™ and the RBIP-ST30™ readout accessory have been demonstrated to be substantially equivalent to, and therefore, as safe and effective as the legally marketed devices: 3M Attest™ 1292, Rapid Readout Biological Indicator for Steam (K090569), and 3M Attest 490 Auto-reader (K103277), respectively.

Conclusion

The BCR-30-min BI™ Biological Indicator and the RBIP-ST30™ readout accessory meet all applicable performance standards and are substantially equivalent to their predicate devices in terms of their intended use, physical properties and technological characteristics.