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Tab 11
510(k) Summary

Section 21 CFR §807.92:

MAY 14 2010

510(k) Notification
Smart-Read™ EZTest® – Steam biological indicator monitor for steam sterilizers

Submitted by:

SGM Biotech, Inc.
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Contact:

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This summary was prepared on 26 Apr 2010 [as required by Section 807.92(a)(1)]

DEVICE:

Classification Name: Indicator, Biological Sterilization Process

Trade name: Smart-Read™ EZTest® - Steam biological indicator
Common name: Self-contained biological indicator for steam [as required by Section 807.92(a)(2)]

CLASSIFICATION: Class II (General Hospital/General Controls)

SUBSTANTIALLY EQUIVALENT OT THE FOLLOWING LEGALLY MARKETED DEVICES:

EZTest® – steam – SGM Biotech, Inc. (K930682)
EZTest® - steam – SGM Biotech, Inc. (K963841)
[as required by Section 807.92(a)(3)]

DESCRIPTION OF DEVICE: Smart-Read EZTest – steam [as required by Section 807.92 (a)(4)]

The biological indicator consists of a self-contained unit which includes: bacterial spores inoculated onto a paper carrier, a small glass ampoule containing sterile culture medium and color indicator, and a plastic vial that serves as the culture tube. This unit complies to the performance characteristics described in USP 31 and ANSI/AAMI/ISO 11138-1.

Spores

Bacterial endospores of *Geobacillus stearothermophilus*, ATCC 7953 or equivalent, are inoculated onto a 591 Whatman filter paper carrier[1] cut into ¼" x ¾" strips to be placed inside the plastic body of the device. The population of spores on each individual piece of paper will be between $1.0 \times 10^{(x)}$ and $5 \times 10^{(x)}$.

The spore concentration will be labeled as a 10^5 or 10^6concentration.

The population data is based on the heat shock population assay. The heat shock procedure is 95°C to 100°C for 15 minutes as outlined in USP 31.

Culture Tube

The culture tube is made of a polypropylene. The plastic culture tube is 1.75" in length and 0.34" in OD. The 0.02" wall allows the culture tube to be flexible so that the culture media glass ampoule can be broken to activate the test.

Culture Medium

The culture medium, consisting of a formulated soybean casein digest medium containing bromocresol purple, this medium is filled into ampoules of a Type I borosilicate glass, flame sealed and sterilized. The sealed ampoules are placed into the plastic body with the spore paper.

Filter Paper Vent

The plastic body is closed with a ½" square autoclavable filter paper vent material.

Cap

A polypropylene plastic cap is used to hold the vent material in place. This cap has three small holes in it to allow steam and air to freely move in and out of the body.

[1] Reference USP 21

INCUBATION:

Following exposure to the sterilization process the exposed Smart-Read EZTest is incubated at 60 ± 2°C for 10 hours. If spores have survived (sterilization failure) the unit will turn yellow due to the growth of the surviving spores.

PHYSICAL PERFORMANCE:

Reduced incubation time was established by exposing sets of 100 BIs to a steam process that reduced the spore population to approximately 1 spore per BI. The exposure was acceptable if at least 30 units demonstrated growth and no more than 80 units demonstrated growth. The units were incubated at 60 ± 2°C for 7 days. The reduced incubation time was identified when 97% of the results of the 7 day results were available.

This test was performed with four different spore crops and multiple lots of product from each crop. The data appears below.

Biological Data for Smart-Read Reduced Incubation Time

	Time	7 Hrs.	8 Hrs.	9 Hrs.	10 Hrs.	24 Hrs.	72 Hrs.	168 Hrs.
Crop #1	Partial Cycle #1							
	Positives	0 / 44	22 / 44	36 / 44	43 / 44	44 / 44	44 / 44	44 / 44
	Percent Growth	0%	50.0%	81.8%	97.7%	100%	100%	100%
	Partial Cycle #2							
	Positives	30 / 45	41 / 45	44 / 45	44 / 45	45 / 45	45 / 45	45 / 45
	Percent Growth	66.7%	91.1%	97.8%	97.8%	100%	100%	100%
	Partial Cycle #3							
	Positives	8 / 73	49 / 73	65 / 73	71 / 73	73 / 73	73 / 73	73 / 73
	Percent Growth	11.0%	67.1%	89.0%	97.3%	100%	100%	100%
	Partial Cycle #4							
	Positives	58 / 80	71 / 80	76 / 80	78 / 80	80 / 80	80 / 80	80 / 80
	Percent Growth	72.5%	88.8%	95.0%	97.5%	100%	100%	100%

	Time	7 Hrs.	8 Hrs.	9 Hrs.	10 Hrs.	24 Hrs.	72 Hrs.	168 Hrs.
Crop #2	Partial Cycle #5							
	Positives	32 / 51	51 / 52	52 / 52	52 / 52	52 / 52	52 / 52	52 / 52
	Percent Growth	61.5%	98.1%	100%	100%	100%	100%	100%
	Partial Cycle #6							
	Positives	44 / 53	53 / 53	53 / 53	53 / 53	53 / 53	53 / 53	53 / 53
	Percent Growth	83.0%	100%	100%	100%	100%	100%	100%
	Partial Cycle #7							
	Positives	36 / 73	66 / 73	72 / 73	73 / 73	73 / 73	73 / 73	73 / 73
	Percent Growth	49.3%	90.4%	98.6%	100%	100%	100%	100%

	Time	7 Hrs.	8 Hrs.	9 Hrs.	10 Hrs.	24 Hrs.	72 Hrs.	168 Hrs.
Crop #3	Partial Cycle #8							
	Positives	26 / 48	43 / 48	48 / 48	48 / 48	48 / 48	48 / 48	48 / 48
	Percent Growth	52.4%	89.6%	100%	100%	100%	100%	100%
	Partial Cycle #9							
	Positives	30 / 46	44 / 46	45 / 46	45 / 46	46	46	46
	Percent Growth	65.2%	95.7%	97.8%	97.8%	100%	100%	100%
	Partial Cycle #10							
	Positives	54 / 60	58 / 60	59 / 60	59 / 60	59 / 60	59 / 60	60
	Percent Growth	90.0%	96.7%	98.3%	98.3%	98.3%	98.3%	100%
	Partial Cycle #11							
	Positives	46 / 61	55 / 61	58 / 61	60 / 61	60 / 61	60 / 61	61 / 61
	Percent Growth	75.4%	90.2%	95.1%	98.4%	98.4%	98.4%	100%

	Time	7 Hrs.	8 Hrs.	9 Hrs.	10 Hrs.	24 Hrs.	72 Hrs.	168 Hrs.
Crop #4	Partial Cycle 12							
	Positives	58 / 80	71 / 80	76 / 80	78 / 80	80 / 80	80 / 80	80 / 80
	Percent Growth	72.5%	88.8%	95%	97.5%	100%	100%	100%

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INTENDED USE OF DEVICE: [as required by Section 807.92(a)(5)]

Smart-Read EZTest – Steam self-contained biological indicators (SCBI) are for monitoring the efficacy of pre-vacuum saturated steam sterilization processes. Performance characteristics are established in accordance with USP 31 for the 121°C steam process. Additional pre-vacuum saturated steam sterilization temperatures are also included in the Certificate of Analysis. Smart-Read EZTest – steam SCBIs are also appropriate for use in processes of 132°C, 134°C and 135°C.

The Smart-Read EZTest – steam SCBI is placed into a sterilizer load in a horizontal position in a location that is judged to be the most difficult to sterilize. A sterilization cycle appropriate for the particular type of load is run. Following the sterilization cycle, the operator removes the SCBI from the load and waits approximately 10 minutes until the device has cooled so it can be comfortably handled. The operator then activates the self-contained ampoule by placing it into the activation well in the Smart-Well incubator and gently pulling forward. This action mechanically flexes the side wall of the plastic vial to break the glass ampoule containing the culture medium. The activated Smart-Read EZTest – steam SCBI is then placed in an incubator at **60 ± 2°C for 10 hours** which provides conditions conducive to growth of any bacterial spores which might have survived the sterilization cycle. Microbial growth of the indicator organisms will produce acid in the microbiological culture medium containing bromcresol purple, thus lowering the pH of the solution and invoking a yellow color change of the media components. If sterilization conditions are met the spores have been killed and the media will remain clear and purple at the conclusion of the 10 hour incubation time.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF Smart-Read EZTest – steam COMPARED TO THE CHARACTERISTICS OF THE PREDICATE DEVICE:
[as required by Section 807.92(a)(6)]

Smart-Read EZTest – steam, is similar in type to other products presently in the marketplace whose useful intent is the monitoring of sterilizer efficacy, has been determined to be safe and effective.

Active components of the indicator have been in routine use more than 30 years. They predate the medical device amendment of the Food and Drug Cosmetic Act and are recognized by the United States Pharmacopoeia 31.

The incubation time of 10 hours at 60 ± 2°C meets the requirements of the CDRH guidance "Validating Biological Indicator Incubation Time".

DETERMINATION OF SUBSTANTIALLY EQUIVALENT BASED ON PHYSICAL CHARACTERISTICS:
[as required by Section 807.92 (b)(1)]

A comparison is provided of the Smart-Read EZTest – steam to the legally marketed predicate device describing similarities and differences such as technology and other important characteristics.

A. EZTest – steam (K930682):

Is manufactured in precisely the same manner as the Smart-Read EZTest device. The only difference is the extension of the label claims for an incubation temperature of 60 ± 2°C and a reduced incubation time (RIT) of 10 hours.

B. EZTest – steam (K963841):

This device is exactly the same as the Smart-Read EZTest – steam. The difference is the extension of the label claims for incubation temperature of 60 ± 2°C and the RIT of 10 hours.

DETERMINATION OF SUBSTANTIALLY EQUIVALENCE BASED ON IN USE PERFORMANCE:
[as required by Section 807.92 (b)(2)]

The resistance performance of Smart-Read EZTest – steam is exactly the same as EZTest – steam K930682 and K963841.

CONCLUSION: [as required by Section 807.92 (b) (3)]

Smart-Read EZTest – steam is appropriate for monitoring pre-vacuum steam sterilization processes of 121°C, 132°C, 134°C and 135°C and meets the USP 31, ANSI/AAMI/ISO 11138-1, and ANSI/AAMI ST 59:1999 requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY 14 2010

Re: K093794
Trade/Device Name: Self-Contained Biological Indicator Smart-Read®
EZTest® – Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: April 26, 2010
Received: April 27, 2010

Dear Dr. Gillis:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB 9
Indications for Use

510(k) Number (if known): K093794

Device Name: Self-contained Biological Indicator Smart-Read® EZTest® – Steam

Indications for Use:

Smart-Read EZTest – Steam self-contained biological indicators (SCBI) are for monitoring the efficacy of saturated steam sterilization processes. Performance characteristics are established in accordance with USP 31 for the pre-vacuum 121°C steam process. Additional pre-vacuum saturated steam sterilization temperatures are also included in the Certificate of Analysis. Smart-Read EZTest – steam SCBIs are also appropriate for use in saturated steam processes of 132°C, 134°C and 135°C.

The Smart-Read EZTest – steam SCBI is placed into a sterilizer load in a horizontal position in a location that is judged to be the most difficult to sterilize. A sterilization cycle appropriate for the particular type of load is run. Following the sterilization cycle, the operator removes the SCBI from the load and waits approximately 10 minutes until the device has cooled so it can be comfortably handled. The operator then activates the self-contained ampoule by placing it into the activation well in the Smart-Well incubator and gently pulling forward. This action mechanically flexes the side wall of the plastic vial to break the glass ampoule containing the culture medium. The activated Smart-Read EZTest – steam SCBI is then placed in an incubator at **60 ± 2°C for 10 hours** which provides conditions conducive to growth of any bacterial spores which might have survived the sterilization cycle. Microbial growth of the indicator organisms will produce acid in the microbiological culture medium containing bromcresol purple, thus lowering the pH of the solution and invoking a yellow color change of the media components. If sterilization conditions are met the spores have been killed and the media will remain clear and purple at the conclusion of the 10 hour incubation time.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093794