K091950

JAN 15 2010

Tab 8
510k Summary
(Required by Section 21 CFR §807.92 (c)

Submitted by: SGM Biotech, Inc.
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President

Prepared on: 29 Apr 2009 Revised on: 16 Oct 2009

General Information:

Device Name:

Common or Usual Name: Self-contained Biological Indicator Incubator (SCBI) for steam processes and a microbiological incubator accessory.

Proprietary Name: SGM Biotech EZTest® SCBI (steam) and Smart-Read EZTest Smart-Well® Incubator

Classification Name: This device is an accessory to Biological Sterilization Process Indicators (21 CFR § 880.2800)

Establishment Registration Number: 3023-231

Device Classification: Class II this is an accessory to a Class II medical device.

Classification Panel: General Hospital (80)

Product Code: Accessory to FRC

Predicate Device: Steris® Verify™ Incubator submitted with the Steris Verify SCBI.

Predicate Device 510k Number: K855101

Performance Standards: The Smart-Read EZTest SCBI for monitoring steam sterilization processes complies to the following FDA recognized standards:

- ANSI/AAMI/ISO 11138-1:2006 Sterilization of Health Care Products – Biological Indicators – Part I, General Requirements
- USP 31:2008 Biological Indicator for steam sterilization, self-contained.
- ISO 9001:2000 Quality management systems – Requirements
- 21 CFR § 820.30 "Design Controls"

The Smart-Well incubator complies to the following standards that are not recognized by FDA.

- CAN/CSA-C22.2 No. 61010-1-04 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- UL Std. No. 61010-1 (2nd Edition) – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
- CAN/CSA-C22.2 No. 61010-2-010:04 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-010: Particular Requirements for laboratory equipment for heating of materials
- UL Std. No. 61010A-2-010 (1st Edition) – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-010: Particular Requirements for laboratory equipment for the heating of materials

Intended Use: The EZTest Smart-Well incubator is designed for the incubation of EZTest (steam) self-contained biological indicators (K930682 and K9630682). The Smart-Read EZTest steam SCBI is used to monitor gravity and pre-vac steam sterilization processes at 121° C, 132° C, 134° C and 135° C. The SCBIs should be placed in the sterilizer load at locations that represent difficult to sterilize positions. Following exposure remove the SCBI from the load, wait approximately 10 minutes until the SCBI is cool enough to handle. Place the SCBI in the activation cavity in the Smart-Well incubator and gently tilt forward to fracture the glass media ampoule inside the plastic vial. This mixes the culture media with the spores if any have survived the sterilization process. Remove the SCBI from the activation cavity and place it into one of the eleven incubation cavities. The Smart-Well incubator maintains temperature of 60 ± 2° C which is conducive to growth of *Geobacillus stearothermophilus* spores. The incubation results are either that the SCBI remains purple (negative) indicating no spore growth or the SCBI turns yellow (positive) which means spores were present and grew. When bacterial spores germinate and grow, they shift the pH of the culture medium. This shift in pH provides the visual color change from purple to yellow. Each incubation cavity is provided with an electronic sensor that alerts the user and conveniently documents when this color change occurs. The user then verifies the visual color change. The electronic signals can be sent to a printer which conveniently documents the visual observation.

Device Description: The Smart-Well microbiological incubator is specifically designed for the incubation of the SGM Smart-Read® EZTest® steam self-contained biological

indicator (SCBI). The Smart-Read EZTest biological indicator contains 10^5 spores of *Geobacillus stearothermophilus* derived from ATCC 7953 inoculated onto a paper carrier. The culture medium is a modified soybean casein digest broth containing bromcresol purple and meets growth promotion requirements when inoculated with 100 spores or less (K930683 and K963841). This single temperature incubator uses a heated aluminum block to maintain the desired temperature of 60 ± 2°C. The incubator has a specifically designed cavity in which to insert and activate the non-activated Smart-Read EZTest unit. The Smart-Read EZTest unit is inserted into this cavity and pulled forward to crush the glass media ampoule and activate the unit. This activated Smart-Read EZTest is removed from this cavity and placed into one of the eleven test cavities. Ten cavities are intended for use with exposed test units and one cavity is intended for use with a positive control. The unit is held in the test cavity for the desired duration of the incubation.

The incubator has telltale LED status lights in front of each test cavity. When a Smart-Read EZTest SCBI is placed into the test cavity, the LED is activated and illuminates amber. The LCD screen will display the particular cavity's test status. This message includes specific cavity number, test status and number of whole hours incubated.

The heated aluminum block provides the temperature desired to allow any surviving spores in the Smart-Read EZTest SCBI to germinate and grow. If viable spores are present in the Smart-Read EZTest SCBI, they will germinate and grow. When growth occurs the cells metabolize sugars and shift the pH of the culture medium to an acid pH. When the pH of the medium shifts to acid it will turn from its purple color to yellow. The monitoring of the color of the Smart-Read EZTest BI is accomplished by a very narrow band width LED. This light is absorbed by the purple color of the medium. However, when the media color shifts to yellow, light is transmitted through the sample and detected by a photo diode behind the sample. When a yellow color is present the photo diode is energized. These results are the same as those visually detected by the human eye under conventional incubation conditions. When the electronics in the cavity detect a yellow color (growth), the status LED will shift from amber to red. The LCD screen will indicate the cavity number, positive test status and the whole number of hours incubated when the test status changed.

If there are no viable spores in the Smart-Read EZTest BI, the incubation duration will be completed with no change in color status. The Smart-Read EZTest has been tested in accordance with the FDA CDRH protocol for reduced incubation time and meets a 10 hour incubation claim. Upon expiration of the selected incubation time and no color change was detected (negative); the status LED in front of the cavity will shift from amber to green (no change in purple color). The LCD screen will indicate the cavity number, negative test status and the whole number of hours incubated which is the user selected incubation time duration.

When the test status LED changes from amber to either red or green, an audible prompt is communicated to the user to remove the Smart-Read EZTest SCBI from the cavity and visually observe its color either purple or yellow. The incubator is not making any

decisions as to the acceptability of the test results; it is simply prompting the user to visually observe the samples and make appropriate decisions. The conditions detected by the incubator are 100% verifiable by the user. The results that the Smart-Well incubator yields can be achieved in any microbiological incubator that provides the same environment for the growth of viable spores required by the Smart-Read EZTest SCBI.

The Smart-Well incubator also has the provision to add a printer to document the testing events. The printer will document the change in status of the incubated Smart-Read EZTest unit. Information captured by the printer includes the incubator cell number, incubation start time and date, time of status change, status change condition (positive or negative). The printer has the capability to print user pre-selected descriptions, as a convenience and if desired by the user, which include descriptions of the exposure conditions to which the Smart-Read EZTest SCBI was exposed. These options include the following:

a) cycle temperature
b) cycle type (pre-vac/gravity)
c) cycle exposure time
d) BI lot number
e) sterilizer number
f) user identification

If none of the above information is selected, the printer will leave blanks or print "?" mark to indicate that no information was selected.

The information that is sent to the printer can also be forwarded to a PC or data acquisition network.

The incubator functions exactly as described above if no printer is attached or no connection is made to a PC or data acquisition network.

Substantial Equivalence: The EZTest Smart-Well incubator is substantially equivalent to the Steris Verify™ incubator. The Smart-Well and Verify incubator have the same intended use and similar features which include: incubation of self-contained biological indicators; use of visible light spectra to assist the user in observing the color change to yellow. This is substantially equivalent to the single cavity in the Verify which illuminates a broad spectrum white light to assist the user in observing the color change to yellow. The Smart-Well incubator has a narrow band LED and an electronic sensor in each cavity to indicate a yellow color change. It also has status LEDs for each cavity to indicate 1) test in progress; 2) yellow color observed (positive); and 3) incubation duration timed out with no color change detected (negative). The Smart-Well also has the capability to have a printer to document the timing of status changes in the color of the biological indicator. The printer also provides a convenient means to document each biological indicator tested. SGM has concluded that the function of the Smart-Well incubator is substantially equivalent to the Steris Verify incubator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room–WO66-0609
Silver Spring, MD 20993-0002

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JAN 15 2010

Re: K091950
Trade/Device Name: Smart-Well® EZTest® Incubator
Regulation Number: 21CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: January 4, 2010
Received: January 6, 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.

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,

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 7
Indications for Use

510(k) Number (if known): K091950

Device Name: Microbiological Indicator Smart-Well Incubator

Indications for Use:

The Smart-Well incubator is intended for use with the Smart-Read EZTest self-contained biological indicators (SCBI). The Smart-Read EZTest – steam SCBI is used for monitoring the efficacy of gravity or pre-vac saturated steam sterilization processes. This SCBI contains 10^5 spores of *Geobacillus stearothermophilus* derived from ATCC #7953. Performance characteristics were established in accordance with USP 32 and ISO 11138-1 for the 121°C steam process. Additional saturated steam sterilization conditions are also tested and appear on the Certificate of Analysis for Smart-Read EZTest – steam. These include 132°C, 134°C, and 135°C.

The operational principles of the device are as follows. The Smart-Read EZTest – steam SCBI is placed into a difficult to sterilize position in the load and a sterilization cycle appropriate for the particular type of load is run. As sterilization conditions are met, the bacterial spores are destroyed by logarithmic thermal death principles. 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 places the SCBI in the activation cavity of the Smart-Well incubator. The SCBI is then gently tilted forward towards the operator to fracture the glass media ampoule inside the plastic sleeve. This allows the culture media to mix with any surviving spores in the SCBI. The activated BI is then placed into one of the ten incubator cavities. The Smart-Well incubator provides a constant pre-set temperature of 60 ± 2°C which is conducive to growth of any bacterial spores which may have survived the sterilization process. The unit is also supplied with an NIST traceable thermometer to independently indicate the incubator block temperature. 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 all spores have been killed, the media will remain clear and purple. The media meets the requirements for growth promotion.

When the activated SCBI is placed into one of the incubation cavities the LED in front of the cavity will illuminate amber, which indicates that the incubator electronically recognizes the Smart-Read EZTest SCBI unit for incubation. Each incubation cavity also has an electronic monitoring system that detects if the BI is either purple or yellow.

The Smart-Well incubator can also be supplied with a printer which documents each individual EZTest steam SCBI tested. The printer can also display information that is normally manually entered into a log book. The recommended incubation hold time of 10 hours has been established using the FDA CDRH Reduced Incubation Time protocol. The printer can also be configured to display BI exposure information that includes 1) exposure time and temperature; 2) cycle type; 3) sterilizer number; 4) BI lot number; and 5) user identification. These are optional entries. If no selection is made, the printed report will default to the previously entered information of place a "?" mark or blank indicating no selection was made.

The printed record will always indicate real time and date, incubation cavity being reported, the incubation start time when the SCBI was placed into the incubation cavity, and the time the test status changed. The result options are 1) NEGATIVE (purple) – incubation time completed with no detectable color change in the Smart-Read EZTest unit, 2) POSITIVE (yellow) – time that a yellow color was detected in the Smart-Read EZTest unit, or 3) TESTING – when a printout is requested and event 1) or 2) have not happened. These results are easily verified by the user as performed in all conventional incubators without printers.

The incubated SCBI should be properly disposed of after the results have been properly recorded. The recommended disposal is to "sterilize by steam 121°C for not less then 30 minutes" of follow your institution's practice for disposal or biological waste.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K091950