K963841

"510(k) Summary"

[as required by Section 807.92(c)]

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510(k) Notification

EZTest® - Steam biological indicator monitor for steam sterilizers

Submitted by:

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[as required by Section 807.92(a)(1)]

DEVICE:

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

SUBSTANTIALLY EQUIVALENT TO THE FOLLOWING LEGALLY MARKETED DEVICES:

EZTest® - SGM Biotech, Inc. (K930682)
ATITEST® - PyMaH Corp. (K902344)
ATTEST® - 3M Co. (pre 1976 device)
PROOF® - AMSCO (K801109)
[as required by Section 807.92(a)(3)]

DESCRIPTION OF DEVICE: **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 ampule 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 the USP XXIII.

Spores

Bacterial endospores of *Bacillus stearothermophilus*, ATCC 7953 or equivalent, are inoculated onto a 591 Schleicher & Schuell, Inc. filter paper carrier* cut into strips of a convenient size to be placed inside the plastic body of the device. The population of spores on each individual piece of paper will be between $0.5 \times 10^{(x)}$ and $5 \times 10^{(x)}$.

The spore concentration will be labeled as a 10^5 concentration. The guideline in the general section on sterilization, USP XXI, p. 121, indicates that the population of spores for a 10^5 biological indicator should be between 0.5×10^5 and 5.0×10^5. This is also the SGM Biotech, Inc. specification.

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 XXIII official monographs, P. 205.

* reference USP XXIII p. 204

Culture Tube

The culture tube is made of a polypropylene. The plastic culture tube is a) 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 ampule can be broken to activate the test.

Culture Medium

The culture medium, consisting of a formulated soybean casein digest base, is filled into ampules of Type III pharmaceutical grade glass, flame sealed and sterilized. The sealed ampules are of convenient size to be placed into the plastic body with the spore paper. Following filling, the ampules are exposed to a steam processing cycle to render them sterile. The ampule is a thin wall glass which allows it to be easily crushed when the plastic body is compressed. This provides the spores with nutrient medium for growth.

The culture medium has a pH indicator (bromcresol purple) added to it which appears as a purple color prior to crushing for incubation. When the spores grow, they produce acid and alter the pH. This causes the medium to change to a yellow color. If the medium changes to yellow, viable spores are present and the sterilization process is not acceptable. If the medium remains purple, the spores did not grow, which means they are not viable.

Filter Paper Vent

The plastic body is closed with a ½" disc filter vent material that allows the exchange of gases from the sterilizer or from the environment.

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.

These materials are all compatible with steam sterilization. These materials have no effect on the resistance of the biological indicator. They are similar to those used in the 3M Attest®.

INTENDED USE OF DEVICE:

[as required by Section807.92(a)(5)]

EZTest® - Steam self contained biological indicators are for monitoring the efficacy of saturated steam sterilization processors. Performance characteristics are established in accordance with USP XXIII for the 121°C steam process. Additional saturated steam sterilization conditions are also included in the Certificate of Performance. **EZTest® - Steam** BIs are also appropriate for use in the high temperature saturated steam processes of 132°C , 134°C and 135°C.

The operational principles of the device are as follows. The **EZTest® - Steam** indicator is placed into a sterilizer load and an appropriate sterilization cycle is run. As sterilization conditions are met, the bacterial spores are destroyed by logarithmic thermal death principles. Following the sterilization cycle, the BI is removed from the load, the operator activates the self-contained ampule by mechanically flexing the side wall of the plastic vial or by using the plastic crusher provided to break the glass ampule containing the culture medium. The activated **EZTest® - Steam** BI is then placed in an incubator which will provide temperatures 55°C to 60°C which is conducive for 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 and/or cloudy color change of the media components. If all spores have been killed the media will remain clear and purple.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF **EZTest® - Steam** COMPARED TO THE CHARACTERISTICES OF THE PREDICTATE DEVICE:

[as required by Section 807.92(a)(6)]

EZTest® - Steam, being 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 20 years. They predate the medical device amendment of the Food and Drug Cosmetic Act and are recognized by the United States Pharmacopoeia XXIII.

Spores of *Bacillus stearothermophilus* are the microorganisms of choice for the evaluation of steam sterilization processes because of their high degree of resistance to this type of processes. The USP XXIII specifically indicates that this species of microorganism be used to monitor steam sterilization process. Numerous biological indicators on the marketplace, such as Proof®, Attest®, and ATITest®, use these microorganisms and have proved to be both safe and efficacious.

EZTest® - Steam biological indicators are produced under a manufacturing in-process quality control system to specifications defining exacting parameters for production to assure a consistent product and good manufacturing procedures. Upon completion of production, each lot is inspected and tested to a quality assurance specification to affirm functional conformance to product specifications. A significant portion of the quality assurance specification is testing to the performance characteristics of biological indicators as outlined in USP XXIII. Such compliance is required on each lot prior to release.

DETERMINATION OF SUBSTANTIALLY EQUIVALENT BASED ON PHYSICAL CHARACTERISTICS:

[as required by Section 807.92(b)(1)]

A comparison is provided of the **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 this device. The difference is the extension of the label claims for use in high temperature saturated steam processes of 132°C, 134°C and 135°C.

B. ATITest® PyMaH/ATI (K902344):

This device is exactly the same as the PyMaH ATITest® disclosed in 510(k) notification K902344. The ATITest® was developed by

SGM Biotech for private label to PyMaH/ATI.

C. Attest® 3M - Pre '76 Product:

This device is virtually identical is size and shape to the 3M Attest®. It has virtually the same carrier material for the spores with the same concentration of *Bacillus stearothermophilus* spores (10^5). The volume of culture medium in the crushable glass ampule is similar. The pH indicator is bromcresol purple in the Attest®, as well as the EZTest®. Therefore, when viable spores grow, the color changes from purple to yellow.

The glass of the crushable glass ampule in Attest® is virtually the same as that used in the EZTest®.

The culture medium in the 3M Attest® is a soybean casein digest derived culture medium. EZTest® uses a soybean casein digest derived culture medium. The specific formulation of the SGM Biotech medium is considered proprietary and confidential.

Activation of the 3M Attest® biological indicator devices are performed by compressing the flexible sides of the plastic culture tubes to break the crushable glass ampule containing the culture medium. This is exactly the way **EZTest® -Steam** is activated.

D. PROOF® - AMSCO (K801109):

The **EZTest® - Steam** is similar to the AMSCO PROOF® in that:

1) similar concentration *B. stearothermophilus* spores are used, i.e. 10^5.
2) spores are carried on chromatography grade pure cotton derived filter paper.
3) culture medium is contained in crushable glass ampule.
4) culture medium is a soybean casein digest derived medium.
5) spore growth is detected by lowering the pH of the culture medium. This shift in pH is detected by the addition of a pH indicator to the medium.

DETERMINATION OF SUBSTANTIALLY EQUIVALENCE BASED ON IN USE PERFORMANCE:

[as required by Section 807.92(b)(2)]

The performance of **EZTest® - Steam** was evaluated for the following characteristics (Certificate of Performance - attached):

a. Bacterial spore species
b. Bacterial spore concentration
c. Sample purity
d. Resistance characteristics including:
    1. D values at 121°C, 132°C, 134°C and 135°C.
    2. Survival/Kill times at 121°C, 132°C, 134°C and 135°C.
    3. Z values
e. Claims were evaluated using at least three (3) spore lots using different spore crops and different media lots.
f. Resistance characteristics were evaluated to determine the effect of holding time after the exposure to the sterilant until incubation, upon the recovery of injured spores.
g. Validation of 48 hours incubation read out time following the CDRH guideline.
h. Evaluation of the effect of the pH indicator upon the recovery of injured spores.
i. Validation of the effect of the sterilization process on the ability of the media to support the growth of injured spores.
j. Stability of the product over the eighteen (18) month shelf life claim.

CONCLUSION:

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

EZTest® - Steam is appropriate for monitoring steam sterilization processes of 121°C, 132°C, 134°C and 135°C and **EZTest® - Steam** meets the USP XXIII requirements.