

K962441

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**Summary of "ProSpore Self-contained Biological Indicator"  
for steam sterilization at 121°C**

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**Device name:** ProSpore® self-contained biological indicator

**Classification:** Class II medical device, General Hospital

**Predicate Devices (legally marketed)** Kilit™ (BBL)  
SporView™ (SPSmedical)

**Predicate Devices 510(k) number:** Kilit™(BBL) - Grandfather In\*  
SporView™ (SPSmedical) K905425

**Description**

ProSpore® is a self-contained biological indicator used for determining the efficiency of a 121°C steam sterilization cycle. The device is a *Bacillus stearothermophilus* in a recovery medium of Tryptic Soy Broth with Bromocresol purple, a pH indicator.

**Specifications**

1) BI

**Microorganism:** *Bacillus stearothermophilus* (ATCC # 7953)

**Population:** 1.0 x 10<sup>5</sup> - 4.0 x 10<sup>5</sup> cfu/unit

**Resistance Characteristics:** (for saturated steam at 121°C)

**D-value:** (determined using Spearman - Karber method on pages 43-50).

**Survival time:** (USP XXII, p. 204 - Attachment #9)

= [min] labeled D-value x (log<sub>10</sub> labeled spore count per carrier -2)

**Kill time:** (USP XXII, p. 204 - Attachment #9)

= [max] labeled D-value x (log<sub>10</sub> labeled spore count per carrier +4)

**Incubation period:** 7 days

## 2) Components

**Ampule:** USP type 1, 4-ml flame-seal flint glass ampule

**Culture/recovery medium:** 10 ml of Bromocresol Purple (BCP) stock solution to each liter of Trypticase® Soy Broth (TSB), adjusted to a pH of 7.0 with Sodium Hydroxide (NaOH) and/or Hydrochloric Acid (HCL)

**nutrient:** Trypticase® Soy Broth powder (Becton Dickinson), as per manufacturer's instructions

**neutralizers:** Sodium Hydroxide (NaOH) and Hydrochloric Acid (HCL)

**pH indicator:** Bromocresol Purple (4 grams BCP powder to each liter of deionized distilled water)

## Operational Principles

The ProSpore® ampule is placed with a load in the sterilization chamber, and subjected to a normal steam sterilization cycle. The ampule is then removed and cooled to room temperature. Next, the processed ampule and an unprocessed (control) ampule are placed in incubation for a period of 7 days at a temperature favorable for growth (55° - 60° C. for *B. stearothermophilus*).

During incubation, the available food supply (TSB) and temperature promote growth of viable spore. The growth process may be accompanied by turbidity and/or a release of acidic waste by products which reduce the pH level of the surrounding medium. Bromocresol purple reacts to this reduction by changing in color to or toward yellow

Within 7 days, growth will become evident by a change in color from purple to/toward yellow and/or turbidity in the test ampule. This may be interpreted as a failure to meet the conditions necessary for sterilization, provided these signs are present in the control ampule.

### Statement of similarity to legally marketed (predicate) devices:

ProSpore® is similar in composition and function to Kilt™ and SporView™, as these devices, like ProSpore® combines *Bacillus stearothermophilus* spores and a recovery medium (combined

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with a pH indicator) in a flame-sealed glass ampule for use in determining the efficacy of steam sterilization cycles.

Clinical Tests:

No clinical tests have been performed.

Discussion of results from nonclinical tests:

Testing was performed to validate the labeled claims and performance characteristics for ProSpore®. These included studies on the labeled incubation period, recovery of damaged spores, the effect of the pH indicator on the recovery of injured spores, and the stability of population and D-value after a real time of one year. Test results confirmed that the tested samples conformed to the labeled claims.

Statement of safety and effectiveness:

Based on similar claims and design, and results from the nonclinical studies mentioned above, the ProSpore® biological indicator has been determined to be substantially equivalent and, therefore, as safe and effective to the legally marketed devices Kilit™ and SporView™.

\*Kilit™(BBL) does not have a 510 (k) number. It was marketed under the grandfather clause, which exempts devices in commercial distribution prior to May 28, 1976. We have obtained the results of the Trademarkscan search of the U.S. Patent Office trademark filing showing that the product was introduced into commerce on June 8, 1955 (Attachment 10). The FDA # is M452998.