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

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

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

**Predicate Devices (legally marketed):** ProofPlus™ (AMSCO)

**Predicate Device 510 (k) number:** K915275

**DESCRIPTION:**

ProSporeII® is a self-contained biological indicator used for determining the efficiency of a 121°C steam sterilization cycle. ProSpore II is comprised of a plastic tube housing with a plastic cap. Inside of the tube is a 1 ml glass ampule of growth media consisting of Tryptic Soy Broth and a pH indicator of phenol red. Also inside of the tube housing is a paper spore disc impregnated with a population of  $10^5$  *Bacillus stearothermophilus* spores (ATCC #7953).

**OPERATIONAL PRINCIPLES:**

The plastic cap of the ProSpore II vial has short 'tines' along it's lower edge. When placed on the plastic tube body, the space between the tines allow for the passage of steam into the tube and thus reach the spore disc. A ProSpore II unit is placed inside of the sterilizer along with a load to be sterilized. If all parameters are met for the cycle (exposure time and temperature), the steam entering the ProSpore II capsule will be sufficient to deactivate or kill the spores on the paper disc. Once the cycle is finished, the ProSpore II vial is removed from the sterilizer and the cap is pressed down with ones thumb. This seals the vial. After allowing the unit to cool for 10 to 15

minutes, the sides of the plastic tubes are squeezed which will result in crushing the glass of the media ampule. With this done, the spore disc is now in contact with the recovery media and the ProSpore II unit can be placed in an incubator and incubated at 55 to 60°C for a 7 day period of time. If the spores were killed in the sterilization cycle, the color of the recovery media will not change. If the cycle was 'failed cycle' and failed to kill the spores, the recovery media will change color from red to yellow indicating growth.

The change in color is the result of 'viable' spores germinating and consuming the nutrients provided in the growth media. This consumption process involves the release of nitrogen waste products which lower the pH of the media and increases the acidity which causes the color to change from red to yellow. Detection of failed steam sterilization cycles is facilitated by the use of ProSpore II. The outer label of the ProSpore II plastic tube body has a chemical indicator on the label which changes color when exposed to saturated steam at 121°C thus making it easy to distinguish processed from unprocessed vials.

#### STATEMENT OF SIMILARITY TO LEGALLY MARKETED PREDICATE DEVICE

ProSpore II is similar in composition and function to the 'Legally Marketed Predicate Device' ProofPlus.

- both devices are intended for use in monitoring 'steam sterilization cycles at 121°C
- both devices utilize a USP recommended strain of *B. stearothermophilus* bacterial spore as it's organism of choice for steam resistance characteristics.
- both devices use a paper disc as the spore carrier.
- both devices utilize a plastic vial and cap to house the spore disc and media capsule.
- both devices contain a sealed recovery media ampule made of glass.
- both devices use a pH indicator in the recovery media which turns from red to yellow in color when growth is present.
- both devices require that the recovery media ampule be activated after sterilization by breaking the glass ampule to release the media to come in contact with the spore disc.
- both devices incorporate a 'chemical indicator' on the label which will change color when exposed to steam at 121°C so that exposed ampules or vials can be distinguished from unprocessed vials.

#### DESCRIPTION OF TESTING:

ProSpore II has been tested for Population Stability over an 18 month self-life. This testing included both D-value stability and Population stability with three separate lots of finished product ProSpore II ampules. The recovery media has been tested to show stability in the recovery of 'low numbers' of 'injured spores' over the 18 month shelf-life and the stability of the color change when growth occurred. For all lots tested, the stability of Resistance Characteristics, Spore Population, Media Recovery and overall effectiveness in monitoring routine steam sterilization cycles that has been demonstrated.

CONCLUSION:

Raven's ProSpore II is substantially equivalent in composition and function to the legally marketed predicate device, AMSCO's ProofPlus, for monitoring steam sterilization cycles at 121°C, based on the testing results and analysis of 18 month self-life stability data.