



REDUCED INCUBATION STUDY ON MESA (Omaha Manufacturing Facility) SPORE STRIPS FOR STEAM STERILIZATION

Purpose: The purpose of this study was to provide data to US FDA in a 510(k) submission (#K032914) substantiating a 24-hour reduced incubation claim for Mesa *G. stearothermophilus* Spore Strips for Steam sterilization when used in conjunction with Mesa Modified Tryptic Soy Broth with Bromocresol Purple.

Procedure: The procedure followed was the FDA guidance for validation of Biological Indicator Incubation Time (available as part of draft guidance at www.fda.gov/cdrh/ode/guidance/1320.pdf). A summary of the procedure follows:

1. Determined “partial kill” exposures for three lots of *G. stearothermophilus* spore strips in a Steam BIER Vessel so that after 7 days of incubation 30% to 80% of the BIs from each lot survived.
2. Once the “partial kill” exposures were determined, exposed 100 units from each lot to the appropriate “partial kill” exposure for that lot.
3. After exposure, each spore strip was aseptically transferred into a sterile screwtop test tube containing approximately 5.5 ml of sterile Tryptic Soy Broth with Bromocresol Purple and incubated at 60°C +/- 2°C for seven days. Growth/no growth results were observed and recorded every 24 hours.
4. At the end of the seven-day incubation period, the shortest incubation period resulting in greater than 97% of the seven-day outgrowth was determined.

Results:

Lot Number	# BIs Tested	# BIs positive on Day 7	# BIs positive after 24 hours
616S	100	76	75
624S	100	66	65
626S	100	70	68

Discussion: In all three lots of Mesa *G. stearothermophilus* Spore Strips tested greater than 97% of units showing outgrowth in seven days showed outgrowth in 24 hours. This meets the greater than 97% required by the protocol to sustain a reduced incubation label claim of 24 hours.

Conclusion: The study intended to establish a reduced incubation claim according to the FDA guidance. For all lots tested, the outgrowth evident at 24 hours was greater than 97% of the total outgrowth at seven days. The above data was included in the 510(k) submission for this product.