TECHNICAL INFORMATION REPORT #1007

REDUCED INCUBATION STUDY ON PROSPORE2 FOR ETHYLENE OXIDE STERILIZATION

Purpose: The purpose of this study was to provide data to US FDA in a 510(k) submission (#K994381) substantiating a 48-hour reduced incubation claim for Raven Prospore2 for EO sterilization.

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procedure followed was the FDA guidance for validation of Biological Indicator Incubation Time (available as part of draft guidance at www.fda.gov/cdrh/ode/guidance/1320.pdf).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" cycles for three lots of Prospore2 EO in an Ethylene Oxide BIER vessel so that after 7 days of incubation 30% to 80% of the BIs from each lot survived.
2. Once the "partial kill" cycles were determined, exposed 100 units from each lot to the appropriate "partial kill" cycle for that lot.
3. After exposure, all units were sealed and activated according to the user instructions and incubated at 30-35^{o}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 48 hours
147GB	100	70	70
153GB	100	32	32
154GB	100	63	63

Discussion: In all three lots of Raven Prospore2 tested, 100% of units showing outgrowth in seven days showed outgrowth in 48 hours. This exceeds the greater than 97% required by the protocol to sustain a reduced incubation label claim of 48 hours.

Conclusion: The study intended to establish a reduced incubation claim according to the FDA guidance. For all lots tested, the outgrowth evident at 48 hours was 100% of the total outgrowth at seven days. The above data was included in the 510(k) submission for this product.