



TECHNICAL INFORMATION REPORT #1002

REDUCED INCUBATION STUDY ON PROSPORE2 FOR STEAM STERILIZATION

Raven Biological Laboratories has performed and confirmed a 24-hour reduced incubation validation for Prospore2 Steam Biological Indicators.

In Raven's 510(k) submission #K971430 approved June 2, 1997 for 48-hour reduced incubation for Prospore2 Steam, a 24-hour reduced incubation was substantiated; however, at that time, industry standard for self-contained biological indicator incubation time was 48 hours. In order to provide a more competitive product, Raven has reviewed the initial reduced incubation data and performed a re-validation of the 24-hour incubation claim.

Both the initial validation and the re-validation were performed in accordance with FDA Guide for Validation of Biological Indicator Incubation Time (available as a part of a new draft guidance at www.fda.gov/cdrh/ode/guidance/1320.pdf). Three lots of Prospore2 units were used in each validation. Partial steam sterilization cycles in a BIER vessel were run to achieve a 30-80% survival for each lot of BI's. Prospore2 units were then incubated at 55-60°C for seven days. Units were checked daily for growth and results recorded. Proposed incubation time is acceptable if more than 97% of the BI's grown out in seven days have grown out in the proposed time interval. In both the initial validation and the re-validation growth after 24 hours was 100% of growth recorded after seven days of incubation.

Re-validation of a 24-hour incubation was performed in July-August 2001. Three additional lots of Prospore2 were tested for the 24-hour reduced incubation. A summary of the results is shown in Table 1.

Lot Number	# BI's Tested	# BI's Positive on Day 7	# BI's Positive After 24 Hours	Date Tested
473	100	60	60	7/27/01
478	100	49	49	7/26/01
482	100	42	42	8/2/01

Table 1

Based on the results summarized in Table 1 and the results from 510(k) #K971430, Raven Biological Laboratories has validated a 24-hour reduced incubation claim for Prospore2 Steam Biological Indicator.