MDT
Technology for Life

MAY 23 1996 K960777

MDT Biologic Company

1777 East Henrietta Road (14623) P.O. Box 23077 Rochester, New York 14692-3077 U.S.A. Telephone (716) 475-1400 Facsimile (716) 272-5271

510(k) SAFETY AND EFFECTIVENESS SUMMARY

for

MDT Biologic Company

UNISPORE® and SPOR-TEST®

Biological Indicators

Submitted by

MDT Biologic Company
1777 East Henrietta Road
Rochester, New York
14692-3077

Phone 716-475-1400
Fax 716-272-5033

Charles O. Hancock
Senior Manager
Regulatory Compliance
Phone 716-272-5080
Fax 716-272-5271

Ref. 21 CFR 807.92(a)(1) & (c)

This summary is for the:

Trade name	MDT Biologic Company Unispore® and Spor-Test®
Common name	Biological Indicators
Classification name	Sterilization Process Biological Indicators (21 CFR 880.2800)

ref. 21 CFR 807.92(a)(2)

We believe this product to be substantially equivalent to the Unispore® and Spor-Test® biological indicators currently having market clearance in accordance with K792649 & K801152 and K800482, & K801980 respectively.

ref. 21 CFR 807.92(a)(3)

The MDT Biologic Company Unispore® and Spor-Test® Biological Indicators are intended to be used for the monitoring of sterilization processes in health care facilities. A biological indicator is a calibrated population of bacterial spores (of high resistance to the sterilization process monitored) on or in a carrier, put up in a package which maintains the integrity of the inoculated carrier and which is of convenience to the ultimate user, that serves to demonstrate whether sterilization conditions are met. The predicate devices were required to be stored under refrigerated conditions. This submittal presents data substantiating storage either under refrigerated conditions or under controlled room temperature conditions. It is further shown that since Unispore® and Spor-Test® biological indicators are manufactured under identical conditions using the same strain of test organisms, the same carrier, the same outer packaging, and the same recovery medium, that Unispore® biological indicators be used to monitor chemical vapor sterilization.

ref. 21 CFR 807.92 (a)(4), (5) & (6)

Between December 1992 and March 1995 MDT Biologic Company conducted a series of shelf life stability studies with different lots each of Unispore® dual-species paper strip biological indicators and Spor-Test® paper strip biological indicators. In addition, both Unispore® and Spor-Test® biological indicators were cultured with MDT's proprietary Culturing Set Medium. Samples of both indicators were qualified for use in both steam and chemical vapor sterilization then placed under freezer (0°C), refrigerator (2°C - 8°C), and controlled room temperature (15° - 30°C) conditions. Population analysis was conducted for all lots at each sampling interval. Each lot was sampled at intervals according to test protocol. Testing was conducted according to Standard Operating Procedures for spore population, steam resistance, and chemical vapor resistance. In addition to testing in steam and chemical vapor BIER (Biological Indicator Evaluator Resistometer) units, limited endpoint bracket testing was also conducted. The formaldehyde content of each lot of Vapo-Steril® employed in testing was confirmed. From the

results of these tests we conclude that both Unispore® and Spor-Test® labeling be modified to: 1) Revise the recommended storage conditions from freezer storage to refrigerator storage; 2) Revise the recommended storage conditions when employed with MDT's Culturing Service (mailer service) to storage in a cool, dry place or refrigeration; and 3) Revise the labeling of Unispore® to include a claim for use with chemical vapor sterilization.

ref. 21 CFR 807.92(b)(1), (2) & (3)
