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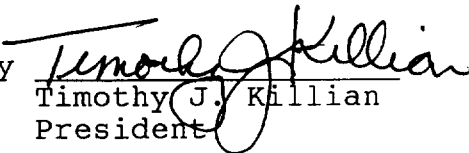
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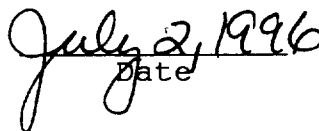
SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS UPON WHICH AN
EQUIVALENCE DETERMINATION COULD BE BASED

Prior to 1976, the Young Rubber Company produced natural latex prophylactics without a reservoir end that were sold both as ultrasound probe covers and natural latex condoms. Carter-Wallace, Inc. in 1986 acquired the Young Rubber Company and continued this production of condoms and ultrasound probe covers, aka endocavity ultrasound transducer natural latex sheaths. In 1987, Kiltex Corporation began producing natural latex prophylactics for Carter-Wallace using the identical formula and equipment as used by Carter-Wallace. In August 1992, CIVCO Medical Instruments Co., Inc. contracted with Kiltex Corporation to manufacture under their (CIVCO's) 510(K) #K895614 natural latex prophylactics to be sold and used solely as ultrasound probe covers. These probe covers are identical to those formerly (prior to August 1992) manufactured by Carter-Wallace, Inc. for CIVCO Medical Instruments Co., Inc. Since August 1992, CIVCO Medical Instruments Co., Inc. has continually marketed and sold Kiltex's production of probe covers.

To date, there is no ASTM or FDA written standard for probe covers. However, the Kiltex ultrasound probe covers have been manufactured to meet the standards for latex condoms as set forth in ASTM D-3492.

Kiltex Corporation

by 
Timothy J. Killian
President


Date