

**SECTION 14 SMDA SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the written requirements of SMDA 1990 and 21 CFR 807.92

**SAFETY AND EFFECTIVENESS OF EXPANDACELL™ INSTRUMENT WIPE**

The Expandacell Instrument Wipe is identical to existing medical devices, K920355, K791736 and K891101. These Instrument Wipes, marketed by Ultracell, Xomed/Merocel and Smith and Nephew have a proven track record that establishes this product line as safe and effective for use in surgery. There is no modification in the proposed device and the predicate devices. The proposed product is identical in intended use, materials, anatomical sites, target population, physical safety, biocompatibility and performance to the predicate device stated.

Sarah Maxwell Luke  
Signature

February 12, 1996  
Date

filename: 510kWIPE.doc