

K964334

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™ ANTI-FOG INSTRUMENT WIPE**

DEC 9 1996

The Expandacell™ Anti-Fog Instrument Wipe is identical to an existing medical device, K923843/A and K791736. These Anti-Fog Instrument Wipes, marketed by Xomed/ Merocel and Dixide, Inc. 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 that alters safety and effectiveness. 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 Lake

Signature: Sarah Maxwell Lake
Regulatory Affairs, Shippert Medical Technologies Corporation

10/30/96

Date

filename: 510kAFOG.doc