

NOV 29 1996

K964269

9. **SUMMARY OF SAFETY AND EFFECTIVENESS**

- ▶ TSST-1, Toxin testing was conducted; results are in the range of values of commercially sold tampons and there are no significant differences between Playtex Tampons #29696 and the predicate device
- ▶ Dioxin Analysis
- ▶ Primary Dermal Irritation in Rabbits - Non-Irritating
- ▶ Acute Oral Toxicity in Rats - Non-Toxic
- ▶ Subacute Vaginal Irritation in Rabbits - Non-Irritating
- ▶ Human Repeat Insult Patch Test - Non-Irritating and not a Sensitizer
- ▶ Agar Diffusion Study - No zones of inhibition were detected