

K955464

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TACTYL TECHNOLOGIES, INC.

2595 COMMERCE WAY  
VISTA, CA 92083  
TEL. (619) 598-2233  
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# Powder Free Examination Glove 510(k) Summary

**DUPLICATE**

## A. SUBSTANTIAL EQUIVALENCE:

Substantial equivalence is shown by comparing the subject device, a powder-free examination glove, to a previously marketed device with 510(k) clearance. The following information is submitted in compliance of a 510(k) summary as required by 21 CFR 807.92

- 1. Submitted by: Tactyl Technologies, Inc. **APR 25 1996**  
(& Manufactured by) 2595 Commerce Way  
Vista, CA 92083
  
- Date Prepared: 12 April, 1996
  
- 2. Facility Registration: 2027921  
Classification Name: 80LYY  
Common Name: Powder Free Examination Glove  
Proprietary Name: TACTYLON™ Powder Free Examination Glove
  
- 3. Substantially Equivalent Device: TACTYLON™ Examination Glove [510(k) K905109]
  
- 4. Marketed by: Tactyl Technologies, Inc.  
2595 Commerce Way  
Vista, CA 92083
  
- Other firms may market the product under a private label agreement and sell under their own brand, one such firm is:
  
- SmartCare  
3400 East McDowell  
Phoenix, AZ 85008-7899
  
- 5. Device Class: I
  
- 6. Contact Person: Jorge Haider  
Director of Regulatory Affairs & Quality Assurance

