

K955419

TACTYL TECHNOLOGIES, INC.

K955419

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APR 15 1996

Powder Free Sterile Surgical Glove 510(k) Summary

A. SUBSTANTIAL EQUIVALENCE:

Substantial equivalence is shown by comparing the subject device, a powder-free surgical 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.
(& Manufactured by) 2595 Commerce Way
Vista, CA 92083

Date Prepared: 8 April, 1996
2. Facility Registration 2027921
Classification Name: 79KGO
Common Name: Powder Free Surgical Glove
Proprietary Name: TACTYLON™ Powder Free Surgeons Glove
3. Substantially Equivalent
Device: TACTYLON™ Surgical Glove [510(k) K902831]
TACTYLON™ Powder Free Surgical Glove
[510(k) K950185]
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

B. DEVICE DESCRIPTION:

Tactyl's powder free surgical gloves are manufactured using TACTYLON™. TACTYLON™ gloves are made of a synthetic material that mimics latex but contain no natural rubber latex. It is also powder free for those users who will benefit from such requirements. The glove meets the physical property requirements of ASTM 3577-91 Rubber Surgical Gloves, Type II, compounded from a rubber cement or from synthetic rubber latex. The surgical glove is intended to be worn by operating room personnel to protect a surgical wound from contamination.

C. COMPARISON TO TACTYLON™ SURGICAL GLOVE:

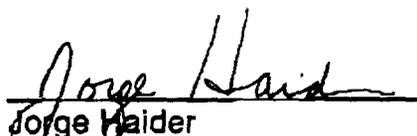
The powder free glove has dramatically reduced powder levels from its equivalent, TACTYLON™ surgical glove. The powder free glove has an added coat of material that is treated to provide donning characteristics without having to use corn starch. The physical properties of the glove remain well within the requirements established by ASTM 3577 and remain comparable to TACTYLON™ surgical gloves.

The product is tested to and has passed the FDA test for water tightness using 1000 ml of water as called for in 21 CFR 800. This test requires gloves to be mounted on a test fixture and 1000 ml of water must be added.

Leakage is defined as water escaping through the glove in any area of the glove, except the top 1½ inches that is attached to the mounting fixture. Any leakage occurring after two minutes is considered a failure. Gloves must pass an Acceptable Quality Level (AQL) of 2.5% as defined in 21 CFR 800.

D. CLINICAL AND NON-CLINICAL TESTING AND THEIR CONCLUSIONS:

Various biocompatibility tests were successfully performed. Delayed Contact Sensitization Study (Repeated Patch Method) was performed in the Guinea Pig and showed no evidence of causing delayed dermal sensitization in the guinea pig. Another test conducted was the Primary Skin Irritation Test (FHSA) in the New Zealand white albino rabbit. The test demonstrated the glove not to be a primary skin irritant.



Jorge Haider
Director of Regulatory Affairs
and Quality Assurance

10 April 96
Date