



K961602

510(k) SUMMARY OCT - 7 1996
01.04.1996

1.0 APPLICANT:

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FDA/CDRH/ODE/DNC

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2.0 CONTACT PERSON

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3.0 Device Class: I

Product code: 80LYY

4.0 Specification: Class I Latex patient examination glove (^{Pink} color)-80LYY
meets all of the requirements of ASTM standard D3578-95

5.0 Device Description: Latex Patient Examination glove (^{Pink} color)

6.0 Intended use: A glove is worn on the hand of healthcare and similar personnel to prevent contamination between healthcare personnel and the patient's body, fluids, waste, or environment

7.0 Inner surface: Pre-powder

8.0 Guinea pig Sensitization (Buehler): Prince of Songkla University, Department of Pharmacology
Faculty of Science: Experiment Reference number T95-02

Guinea pig sensitization (Buehler) "There was no evidence of sensitization in both induced (test) guinea pigs and control groups. The results suggest that the risk of contact sensitization in human should be minimal"



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9.0 QUALITY CHARACTERISTICS

DESCRIPTION	ASTM standard	SPECIFICATION
DIMENSION Overall length Width (double wall) Thickness, mm Finger palm	S-2 AQL 4.0 230 min. S 80 +/- 10 mm M 95 +/- 10 mm L 111 +/- 10 mm 0.08 mm MIN. 0.08 mm MIN.	S-2 AQL 4.0 240+/-10 mm SS 77 +/- 5 mm S 83 +/- 5 mm M 94 +/- 5 mm L 105 +/- 4 mm 0.08 mm MIN. 0.08 mm MIN.
PHYSICAL PROPERTIES Before aging Tensile strength Elongation at break After aging Tensile strength Elongation at break	S-2 AQL 4.0 14 Mpa MIN. 700 % MIN. 14 Mpa MIN. 500% MIN.	S-2 AQL 4.0 14 Mpa MIN. 700% MIN. 14 Mpa MIN. 500% MIN.
POWDER LEVEL Inside Outside	N/A	S-2 AQL 4.0 2.5+/-1.0% 1.0% MAX.
FREEDOM FROM HOLE	S-4 AQL 4.0	II AQL 1.5

10. Conclusion: Siam Sempermed Latex Patient Examination Glove (^{PINK} color)
meet ASTM standard
meet pinhole FDA requirements
meet labeling claims (see 5.0 and 6.0 above)

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