



SEP 17 1996

510(k) SUMMARY

07.02.1996

1.0 APPLICANT:

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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 (Hypoallergenic)-801.YY
meets all of the requirements of ASTM standard D3578-95

5.0 Device Description: Latex Patient Examination glove (Hypoallergenic)
50 micrograms or less of total water extractable protein per gram of glove

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 Outer surface: Free from talc (Magnesium silicate)

8.0 Human Repeat Insult Patch Test: Concordia Research Laboratories, Inc. Study Number: SAT-001 A N/E

"From the complete lack of reactions noted during the Elicitation Phases (Challenge) of this test, it is evident
that the irritation and allergenic potential of the test article is extremely low, If existent at all

It is the opinion of the undersigned that this product can be safely distributed for its intended use"

Primary Dermal Irritation in Rabbits Guinea Pig Sensitization (Buehler): Consumer Product Testing Co.
Experiment reference number T95-0189-1.

"According to Federal Hazardous Substances Act Regulations, (16 CFR 1500.41), and under the conditions of
this test, this test article is not a primary dermal irritant".



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9.0 QUALITY CHARACTERISTICS

DESCRIPTION	ASTM standard	SPECIFICATION
DIMENSION	S-2 AQL 4.0	S-2 AQL 4.0
Overall length	230 min.	240+/-10 mm
Width (double wall)	S 80 +/- 10 mm M 95 +/- 10 mm L 111 +/- 10 mm	SS 77 +/- 5 mm S 83 +/- 5 mm M 94 +/- 5 mm L 105 +/- 4 mm
Thickness, mm		
Finger	0.08 mm MIN.	0.08 mm MIN.
palm	0.08 mm MIN.	0.08 mm MIN.
PHYSICAL PROPERTIES	S-2 AQL 4.0	S-2 AQL 4.0
Before aging		
Tensile strength	14 Mpa MIN.	14 Mpa MIN
Elongation at break	700 % MIN.	700% MIN.
After aging		
Tensile strength	14 Mpa MIN.	14 Mpa MIN.
Elongation at break	500 % MIN.	500% MIN.
WATER EXTRACTABLE PROTEIN	N/A	S-2 AQL 4.0 50 ug/g MAX.
POWDER LEVEL	N/A	2.5 +/- 1.0 by weight
FREEDOM FROM HOLE	S-4 AQL 4.0	II AQL 1.5

10. Conclusion: Siam Sempermed Latex Patient Examination Glove (Hypoallergenic)
meet or exceed the ASTM standard or equivalent standard
meet pinhole FDA requirements
meet labeling claims (see 5.0 and 6.0 above)

P. Cherdkiatgumchai

Dr. POONSUK CHERDKIATGUMCHAI
Senior Assistant Chief Production Officer (quality)

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