

**K994248 SENSI-PRO, DISPOSABLE PRE-POWDERED
SYNTHETIC VINYL PATIENT EXAMINATION GLOVES WITH
BEIGE PIGMENT ADDITIVES**Jan 28, 2000
43 days to decisionK994248 · Product code: LYZ · General Hospital
Source: <https://www.510kdatabase.net/k994248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Dec 16, 1999
Decision date	Jan 28, 2000
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Shinemound Enterprise, Inc.
Location	North Billerica, MA, US
Contact	HUAN-CHUNG LI
510(k) history	8 submissions · 8 cleared · 1997-2005

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