

K971360 SYNTEXDec 22, 1997
255 days to decisionK971360 · Product code: **LYZ** · General Hospital
Source: <https://www.510kdatabase.net/k971360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Apr 11, 1997
Decision date	Dec 22, 1997
Days to decision	255 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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