FDA 510(k) Premarket Notification

K051913 POWDERED LATEX PATIENT EXAMINATION GLOVES

CLEARED

Sep 30, 2005
77 days to decision

K051913 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k051913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 15, 2005
Decision date	Sep 30, 2005
Days to decision	77 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