

K113685 POWDER FREE LATEX EXAMINATION GLOVESAug 10, 2012
239 days to decision

K113685 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k113685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 15, 2011
Decision date	Aug 10, 2012
Days to decision	239 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Khai Hoan Joint Stock Company
Location	Binh Duong Province, VN
Contact	TERENCE LIM
510(k) history	2 submissions · 2 cleared · 2010-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113685/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 14, 2026