

K030112 POWDER FREE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM LESS THAN 50 MICROGRAM OR LESS OF TOTAL WATER EXTRACTABFeb 27, 2003
45 days to decisionK030112 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k030112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jan 13, 2003
Decision date	Feb 27, 2003
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Smartglove Indonesia
Location	Tg Morawa-Deli Serdang Utara, ID
Contact	FOO KHON PU
510(k) history	12 submissions · 12 cleared · 2003-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030112/> 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 6, 2026