

**K012714 ROYAL IMPERIAL POWDER FREE POLYMER COATED  
LATEX EXAMINATION GLOVE WITH PROTEIN CONTENT  
LABELING CLAIM (50 MICROGRAMS OR**

Oct 31, 2001  
78 days to decision

K012714 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k012714/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 14, 2001
Decision date	Oct 31, 2001
Days to decision	78 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Koon Seng Sdn Bhd</b>
Location	81707 Pasir Gudang, Johor, MY
Contact	LIM WENG HENG
510(k) history	7 submissions · 7 cleared · 1989-2021

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k012714/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026