

**K980807 NITRILE EXAMINATION GLOVES- POWDERFREE
(SMALL, MEDIUM AND LARGE)**Apr 2, 1998
36 days to decisionK980807 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k980807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 25, 1998
Decision date	Apr 2, 1998
Days to decision	36 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Eka Wira Asia
Location	Medan 20112 - Indonesia, ID
Contact	EMMY TJOENG
510(k) history	3 submissions · 3 cleared · 1994-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980807/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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