

K090828 NON-STERILE, POWDER FREE NITRILE EXAMINATION GLOVES

Jul 28, 2009
124 days to decision

K090828 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k090828/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 26, 2009
Decision date	Jul 28, 2009
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ultrawin Sdn Bhd
Location	Malaysia, MY
Contact	MAH SIEW HOE
510(k) history	5 submissions · 5 cleared · 1992-2009

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090828/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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