

**K081971 BIOCLEAR CHEMO ULTIMATE POWDER FREE
POLYCHLOROPRENE EXAMINATION GLOVES**Dec 23, 2008
166 days to decisionK081971 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k081971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Jul 10, 2008
Decision date	Dec 23, 2008
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nitritex (M) Sdn. Bhd.
Location	Kuala Langat, Selangor De, MY
Contact	DEREK WATTS
510(k) history	3 submissions · 3 cleared · 2008-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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