

K081970 BIOCLEAN CHEMO SHIELDMar 11, 2009
244 days to decisionK081970 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k081970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 10, 2008
Decision date	Mar 11, 2009
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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