

K981333 NITRILON CORRECT-TOUCHJun 22, 1998
70 days to decisionK981333 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k981333/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 13, 1998
Decision date	Jun 22, 1998
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biopro (M) Sdn Bhd
Location	San Luis Obispo, CA, US
Contact	MIKE KYLE
510(k) history	5 submissions · 5 cleared · 1998-2000

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