

K010438 MAXITEX DUPLEX POWDER FREE LATEX STERILE SURGEON GLOVES PROTEIN LABELING CLAIM (50 MICRGRAMS OR LESS)May 1, 2001
77 days to decisionK010438 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k010438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 13, 2001
Decision date	May 1, 2001
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terang Nusa Sdn Bhd
Location	68100 Batu Caves Selangor, MY
Contact	CHIN-GUAN LOW
510(k) history	26 submissions · 26 cleared · 1989-2017

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