

K010439 MAXITEX DUPLEX STERILE LATEX POWDERED SURGEON GLOVES WITH PROTEIN LABELING CLAIM (100 MICROGRAMS OR LESS)

May 1, 2001
78 days to decision

K010439 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k010439/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 12, 2001
Decision date	May 1, 2001
Days to decision	78 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k010439/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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