

**K140355 SENSIFLEX PLUS STERILE LATEX SURGICAL GLOVE
POWDERFREE WITH PROTEIN CONTENT LABELING CLAIM**Nov 6, 2014
267 days to decisionK140355 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k140355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 12, 2014
Decision date	Nov 6, 2014
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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