

K161008 POLYISOPRENE POWDER FREE SURGICAL UNDERGLOVE, POLYISOPRENE POWDER FREE SURGICAL GLOVE

Jul 28, 2016
108 days to decision

K161008 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k161008/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 11, 2016
Decision date	Jul 28, 2016
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k161008/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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