

**K183389 Polyisoprene Powder Free Surgical Glove,
Polyisoprene Powder Free Surgical Underglove**

Jun 28, 2019
204 days to decision

K183389 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k183389/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 6, 2018
Decision date	Jun 28, 2019
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	Kuan Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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