

**K211758 Polychloroprene Powder Free Examination Glove
Tested for Use with Chemotherapy Drugs (Fusion Colour)**Aug 3, 2021
57 days to decisionK211758 · Product code: **OPC** · General Hospital
Source: <https://www.510kdatabase.net/k211758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder-free Polychloroprene Patient Examination Glove (OPC)
Date received	Jun 7, 2021
Decision date	Aug 3, 2021
Days to decision	57 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 Mun Leong
510(k) history	28 submissions · 28 cleared · 2014-2025

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