

K200915 Powder Free White Sterilized Polyisoprene Surgical Gloves-Tested for Use with The Chemotherapy DrugsJul 9, 2021
459 days to decisionK200915 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k200915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 6, 2020
Decision date	Jul 9, 2021
Days to decision	459 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Gx Corporation Sdn Bhd
Location	Klang, Selangor, MY
Contact	Khon Pu Foo
510(k) history	18 submissions · 18 cleared · 2007-2021

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