

K260558 Latex Powder Free Surgical Gloves Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

Jul 28, 2026
159 days to decision

K260558 · Product code: KGO · General Hospital
Source: <https://www.510kdatabase.net/k260558/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 19, 2026
Decision date	Jul 28, 2026
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary
Other names	Latex Powder Free Surgical Gloves with Colloidal Oatmeal Tested for Use with Chemotherapy Drugs and Fentanyl Citrate

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	Kuan Mun Leong
510(k) history	31 submissions · 31 cleared · 2014-2026