

K171279 Sterile Nitrile Surgical Powder Free Gloves Tested for Use with Chemotherapy Drugs and Sterile Latex Surgical Powder Free Gloves

Oct 12, 2017
164 days to decision

K171279 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k171279/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 1, 2017
Decision date	Oct 12, 2017
Days to decision	164 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Top Glove Sdn. Bhd.
Location	Malaysia, ML
Contact	Noor Akilah Bt Saidin
510(k) history	17 submissions · 17 cleared · 1991-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171279/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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