

K181047 Powder Free White, Blue Sterilized Nitrile Copolymer Surgical Gloves Tested for Use with Chemotherapy Drugs

Jan 9, 2019
265 days to decision

K181047 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k181047/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Apr 19, 2018
Decision date	Jan 9, 2019
Days to decision	265 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Smart Glove Corporation Sdn. Bhd.
Location	Klang, MY
Contact	Khon Pu Foo
510(k) history	5 submissions · 5 cleared · 2017-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181047/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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