

**K201774 Polychloroprene Powder Free Sterile Surgical Gloves,
Low Dermatitis Potential and Tested for Use with
Chemotherapy Drugs**

Sep 16, 2020
79 days to decision

K201774 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k201774/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 29, 2020
Decision date	Sep 16, 2020
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Medisafe Technologies
Location	Medan, ID
Contact	Sajeev Joseph
510(k) history	19 submissions · 19 cleared · 2001-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k201774/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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