

**K173258 Polychloroprene Powder Free Sterile Surgical Gloves,  
White, Tested for Use with Chemotherapy**Apr 20, 2018  
192 days to decisionK173258 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k173258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Oct 10, 2017
Decision date	Apr 20, 2018
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pt. Medisafe Technologies</b>
Location	Medan, ID
Contact	Deepak Bang
510(k) history	19 submissions · 19 cleared · 2001-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173258/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026