

**K170515 Sterile Nitrile Surgical Gloves, Powder-free**Jun 9, 2017  
108 days to decisionK170515 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k170515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Feb 21, 2017
Decision date	Jun 9, 2017
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Primus Gloves Pvt Limited</b>
Location	Cochin, IN
Contact	Jose Paul M
510(k) history	3 submissions · 3 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170515/> 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 May 31, 2026