

**K192933 Polyisoprene Powder Free, Black Colour Surgical Gloves**Jan 13, 2021  
454 days to decisionK192933 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k192933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Oct 17, 2019
Decision date	Jan 13, 2021
Days to decision	454 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Emerson &amp; Co. Srl</b>
Location	Genoa, IT
Contact	Laura Figliomeni
510(k) history	3 submissions · 3 cleared · 1998-2021

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192933/> 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 27, 2026