

**K191860 Sterile Powder-Free Synthetic Rubber Surgeon's Glove with Low Dermatitis Potential**Mar 31, 2020  
264 days to decisionK191860 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k191860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 11, 2019
Decision date	Mar 31, 2020
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Semperit Technische Produkte Gesellschaft M.B.H.</b>
Location	Wimpassing, AT
Contact	Andreas Woess
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mansour Consulting, LLC</b>
Contact	Jay Mansour

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191860/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026