

**K160781 Sempermed Syntegra IR, Sterile Powder Free Synthetic Rubber Surgeons Gloves**

May 2, 2017  
406 days to decision

K160781 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k160781/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Mar 22, 2016
Decision date	May 2, 2017
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Semperit Investments Asia Pte , Ltd.</b>
Location	Singapore, SG
Contact	CLEMENS EICHLER
510(k) history	4 submissions · 4 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k160781/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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