

**K130450 SURGTEX POWDERED SURGICAL GLOVE, SURGTEX POWDERFREE POLYMER COATED SURGICAL GLOVE**

Sep 30, 2014  
585 days to decision

K130450 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k130450/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Feb 22, 2013
Decision date	Sep 30, 2014
Days to decision	585 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Purna Bina Sdn Bhd</b>
Location	Johor, MY
Contact	ROBERT HILL
510(k) history	7 submissions · 7 cleared · 1989-2014

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

Device record: <https://www.510kdatabase.net/k130450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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