

**K031669 STERILE POWDER FREE SYNTHETIC SURGICAL
GLOVE WITH POLYMER COATING**Sep 23, 2003
117 days to decisionK031669 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k031669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	May 29, 2003
Decision date	Sep 23, 2003
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Saptindo Surgica
Location	Great Neck,, NY, US
Contact	WIDAGDO GONDOWARDOYO
510(k) history	3 submissions · 3 cleared · 1995-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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