

K053443 BIOGEL ECLIPSE NON-PYROGENIC LATEX POWDER-FREE STERILE SURGEON's GLOVE

Feb 1, 2006
54 days to decision

K053443 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k053443/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 9, 2005
Decision date	Feb 1, 2006
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Regent Medical Americas, LLC
Location	Norcross, GA, US
Contact	KATHLEEN HARRIS
510(k) history	7 submissions · 7 cleared · 2005-2006

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Device record: <https://www.510kdatabase.net/k053443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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