

K190782 FlexGard Cut-Resistant Glove LinersJun 27, 2019
92 days to decisionK190782 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k190782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Mar 27, 2019
Decision date	Jun 27, 2019
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ldi Corporation
Location	Portsmouth, NH, US
Contact	Lou LaMarca
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Quality & Regulatory Associates, LLC
Contact	Gary Syring

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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