

K193573 Biogel Skinsense Indicator Underglove, Biogel PI Ultratouch, Biogel PI Indicator Underglove, Biogel PI, Biogel PI Micro

Apr 10, 2020
109 days to decision

K193573 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k193573/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Dec 23, 2019
Decision date	Apr 10, 2020
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Molnycke Health Care Us, LLC
Location	Norcross, GA, US
Contact	Calen Souther
510(k) history	27 submissions · 27 cleared · 2006-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193573/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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