

K202090 Biogel Eclipse / Biogel Eclipse Indicator Underglove, Biogel Surgeons / Biogel Indicator Underglove, Biogel PI Micro Indicator Underglove, Biogel PI UltraTouch S Surgical Glove with a Low Dermatitis Potential Claim, Biogel PI UltraTouch S Indicator Underglove with a Low Dermatitis Potential Claim

Nov 22, 2020
117 days to decision

K202090 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k202090/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 28, 2020
Decision date	Nov 22, 2020
Days to decision	117 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Molnlycke Health Care Us, LLC
Location	Norcross, GA, US
Contact	Leonard Stewart
510(k) history	27 submissions · 27 cleared · 2006-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k202090/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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