

K230384 PolyWear® Personal Protective Level 3 GownAug 11, 2023
178 days to decisionK230384 · Product code: **QPC** · General Hospital
Source: <https://www.510kdatabase.net/k230384/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC)
Date received	Feb 14, 2023
Decision date	Aug 11, 2023
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	PolyConversions, Inc.
Location	Champaign, IL, US
Contact	William Smith
510(k) history	2 submissions · 2 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230384/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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