

K925077 POLY-MED DISP. PERS. PROT. GOWN APRON & SHOECOVERSAug 16, 1993
313 days to decisionK925077 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k925077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Oct 7, 1992
Decision date	Aug 16, 1993
Days to decision	313 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medtek Development Corp.
Location	Bloomington, IL, US
Contact	WILLIAM B SMITH
510(k) history	2 submissions · 2 cleared · 1993-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k925077/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 7, 2026