

K013846 ULTRAGARD IMPERVIOUS REINFORCED GOWNMay 22, 2002
183 days to decisionK013846 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k013846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 20, 2001
Decision date	May 22, 2002
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Precept Medical Products, Inc.
Location	Arden, NC, US
Contact	MARY ANN FAULKNER
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013846/> 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 2, 2026