

K945124 BREAST LESION LOCALIZATION NEEDLENov 22, 1994
34 days to decisionK945124 · Product code: **GDF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k945124/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Needle, Surgical (GDF)
Date received	Oct 19, 1994
Decision date	Nov 22, 1994
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Promex, Inc.
Location	Indianapolis, IN, US
Contact	JOSEPH L MARK
510(k) history	18 submissions · 18 cleared · 1994-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945124/> 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 May 20, 2026