

K944942 BREAST LESION LOCALIZATION NEEDLENov 4, 1994
28 days to decisionK944942 · Product code: **GDF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k944942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Needle, Surgical (GDF)
Date received	Oct 7, 1994
Decision date	Nov 4, 1994
Days to decision	28 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Promedical , Ltd.
Location	Wyckoff, NJ, US
Contact	HENRY V SIERAKOWSKI
510(k) history	5 submissions · 5 cleared · 1994-1995

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