FDA 510(k) Premarket Notification

K945124 BREAST LESION LOCALIZATION NEEDLE

CLEARED

Nov 22, 1994
34 days to decision

K945124 · Product code: **GDF** · General & Plastic Surgery
Source: 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