FDA 510(k) Premarket Notification

K920816 PERCUGUIDE LESION MARKING

CLEARED

Apr 21, 1992
75 days to decision

K920816 · Product code: **GDF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k920816/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Needle, Surgical (GDF)
Date received	Feb 6, 1992
Decision date	Apr 21, 1992
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**E-Z-Em, Inc.**
Location	Mchenry, IL, US
Contact	MARLENE WRIGHT
510(k) history	56 submissions · 56 cleared · 1977-2007