FDA 510(k) Premarket Notification

K000455 GETTIG GUARD

CLEARED

Apr 19, 2000
68 days to decision

K000455 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k000455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 11, 2000
Decision date	Apr 19, 2000
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gettig Pharmaceutical Instrument Co.**
Location	Great Neck, NY, US
Contact	JAMES A BENZ
510(k) history	5 submissions · 5 cleared · 1997-2004