FDA 510(k) Premarket Notification

K780209 DILUTION SPIKE

CLEARED

Apr 10, 1978
63 days to decision

K780209 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k780209/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 6, 1978
Decision date	Apr 10, 1978
Days to decision	63 days
Third-party review	No

APPLICANT

Company	**Sterling Drug, Inc.**
Location	Mchenry, IL, US
510(k) history	9 submissions · 9 cleared · 1978-1990