FDA 510(k) Premarket Notification

K896086 PROGUARD II(TM)

CLEARED

Jan 24, 1990
97 days to decision

K896086 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k896086/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Oct 19, 1989
Decision date	Jan 24, 1990
Days to decision	97 days
Third-party review	No

APPLICANT

Company	**Safety-Ject, Inc.**
Location	Costa Mesa, CA, US
Contact	DENNIS SITAR
510(k) history	2 submissions · 2 cleared · 1990-1990