FDA 510(k) Premarket Notification

K861686 NOVOPEN SYSTEM (INSULIN SYRINGE)

CLEARED

Jan 21, 1987
264 days to decision

K861686 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k861686/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 2, 1986
Decision date	Jan 21, 1987
Days to decision	264 days
Third-party review	No

APPLICANT

Company	**Squibb-Novo, Inc.**
Location	Princeton, NJ, US
Contact	STEPHANIE RAIS
510(k) history	2 submissions · 2 cleared · 1987-1987