FDA 510(k) Premarket Notification

K014088 DUPLOREACH

CLEARED

Jun 7, 2002
177 days to decision

K014088 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k014088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 12, 2001
Decision date	Jun 7, 2002
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corp**
Location	Mchenry, IL, US
Contact	ARLENE VIDOR
510(k) history	505 submissions · 496 cleared · 1977-2019