FDA 510(k) Premarket Notification

K913114 TRIM-PORT(TM) IMPLANT ACCESS SYST DUAL TITAN PORT

CLEARED

Jan 2, 1992
178 days to decision

K913114 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k913114/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 8, 1991
Decision date	Jan 2, 1992
Days to decision	178 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Gerard Medical Enterprises, Inc.**
Location	Mchenry, IL, US
Contact	RICHARD CAYER
510(k) history	8 submissions · 6 cleared · 1981-1996