FDA 510(k) Premarket Notification

K912111 MODIFIED VERSION IMPLANTABLE VASCULAR ACCESS SYSTE

CLEARED

Oct 8, 1991
148 days to decision

K912111 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k912111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 13, 1991
Decision date	Oct 8, 1991
Days to decision	148 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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