FDA 510(k) Premarket Notification

K991758 MONOJECT INSULIN SYRINGE

CLEARED

Jun 14, 1999
21 days to decision

K991758 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k991758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	May 24, 1999
Decision date	Jun 14, 1999
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**The Kendal Co.**
Location	Mchenry, IL, US
Contact	FRANK J FUCILE
510(k) history	63 submissions · 60 cleared · 1980-2000