

K941020 DRUG RECONSTITUTION FILTER DEVICEAug 10, 1994
160 days to decisionK941020 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k941020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 3, 1994
Decision date	Aug 10, 1994
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gelman Sciences, Inc.
Location	Mchenry, IL, US
Contact	MITCHELL L EHRlich
510(k) history	32 submissions · 32 cleared · 1979-1995

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