

K051930 DRUG ACCESS SPIKEAug 16, 2005
34 days to decisionK051930 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k051930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 13, 2005
Decision date	Aug 16, 2005
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Medegen Medical Manufacturing Services
Location	Trabuco Canyon, CA, US
Contact	SALVADORE F PALOMARES
510(k) history	4 submissions · 4 cleared · 2005-2008

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