

K083457 TACTIPENFeb 13, 2009
84 days to decisionK083457 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k083457/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 21, 2008
Decision date	Feb 13, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Haselmeier GmbH
Location	Farmington Hill, MI, US
Contact	STEPHEN J GOLDNER, JD, RAC
510(k) history	2 submissions · 2 cleared · 2008-2009

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