

K090162 EVICEL APPLICATION DEVICEFeb 20, 2009
29 days to decisionK090162 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k090162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Jan 22, 2009
Decision date	Feb 20, 2009
Days to decision	29 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Omrix Biopharmaceuticals , Ltd.
Location	Ramat Gan, IL
Contact	SARA HORN
510(k) history	2 submissions · 2 cleared · 2007-2009

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