

K130900 EVICEL APPLICATION DEVICEAug 13, 2013
134 days to decisionK130900 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k130900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Apr 1, 2013
Decision date	Aug 13, 2013
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon Inc (On Behalf of Omrix Biopharmaceuticals)
Location	Somerville, NJ, US
Contact	SHIKHA GOLA
510(k) history	1 submissions · 1 cleared · 2013-2013

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