

K160797 FMX314 Surgical PlatformAug 26, 2016
156 days to decisionK160797 · Product code: **OTJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscopic Single Port Access Device (OTJ)
Date received	Mar 23, 2016
Decision date	Aug 26, 2016
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fortimedix Surgical B.V.
Location	Nuth, NL
Contact	DIRKJAN BAKKER
510(k) history	1 submissions · 1 cleared · 2016-2016

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