

K111939 M/29TM - PRESSURE INJECTABLEJul 11, 2012
369 days to decisionK111939 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k111939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 8, 2011
Decision date	Jul 11, 2012
Days to decision	369 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Flexicath , Ltd.
Location	Kfar Saba, IL
Contact	TALI HAZAN
510(k) history	4 submissions · 4 cleared · 2007-2012

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