

K141026 LEADERFLEXJul 30, 2014
99 days to decisionK141026 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k141026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 22, 2014
Decision date	Jul 30, 2014
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vygon
Location	Lansdale Montgomery, PA, US
Contact	JILLIAN MIKOVICH
510(k) history	2 submissions · 2 cleared · 2014-2016

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