

K052564 VYGON LEADER-FLEXApr 5, 2006
198 days to decisionK052564 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k052564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Sep 19, 2005
Decision date	Apr 5, 2006
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vygon Corp.
Location	East Rutherford, NJ, US
Contact	COURTNEY SMITH
510(k) history	48 submissions · 46 cleared · 1985-2012

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