

K212370 Leaderflex Mini and Leaderflex NanoAug 29, 2022
395 days to decisionK212370 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k212370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jul 30, 2021
Decision date	Aug 29, 2022
Days to decision	395 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vygon USA
Location	Lansdale, PA, US
Contact	Lauren Doyle
510(k) history	4 submissions · 4 cleared · 2018-2024

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