

K221473 FlowartSep 26, 2022
129 days to decisionK221473 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k221473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 20, 2022
Decision date	Sep 26, 2022
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Asset Medikal Tasarim As.
Location	Istanbul, TR
Contact	Ebru Sirali
510(k) history	4 submissions · 4 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Licensale, Inc.
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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