

K222889 FlowArt® Needle-Free Split Septum ValveJan 20, 2023
119 days to decisionK222889 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k222889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 23, 2022
Decision date	Jan 20, 2023
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Asset Medikal Tasarim San Tic As.
Location	Istanbul, TR
Contact	Ebru Sirali
510(k) history	1 submissions · 1 cleared · 2023-2023

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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