

K230083 SAFIRAOct 31, 2023
293 days to decisionK230083 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k230083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jan 11, 2023
Decision date	Oct 31, 2023
Days to decision	293 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medovate Limited
Location	Girton, GB
Contact	Alan Finnerty
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Delphi Medical Device Consulting, Inc.
Contact	Pamela Papineau

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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