FDA 510(k) Premarket Notification

# K230083 SAFIRA

**CLEARED**

Oct 31, 2023
293 days to decision

K230083 · 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