

K213744 Avoset Infusion Pump SystemMar 10, 2023
466 days to decisionK213744 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k213744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Nov 29, 2021
Decision date	Mar 10, 2023
Days to decision	466 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eitan Medical , Ltd.
Location	Netanya, IL
Contact	Guy Mlechkovich
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Z&B Enterprises, Inc.
Contact	Rhona Shanker

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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