

K201626 Safety Subcutaneous Infusion SetMar 24, 2021
281 days to decisionK201626 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k201626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jun 16, 2020
Decision date	Mar 24, 2021
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Epic Medical Pte. , Ltd.
Location	Singapore, SG
Contact	Freddie Lee
510(k) history	21 submissions · 21 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	QUARAS, LLC
Contact	Roshana Ahmed

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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