

K192860 Sapphire Infusion Pump, Sapphire administration setsNov 19, 2020
412 days to decisionK192860 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k192860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Oct 4, 2019
Decision date	Nov 19, 2020
Days to decision	412 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Q Core Medical , Ltd.
Location	Gaithersburg, MD, US
Contact	Guy Mlechkovich
510(k) history	5 submissions · 5 cleared · 2013-2020

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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