

K141389 SAPPHIRE INFUSION PUMPDec 11, 2014
198 days to decisionK141389 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k141389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	May 27, 2014
Decision date	Dec 11, 2014
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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