

K183311 Ivenix Infusion System (IIS)Jun 7, 2019
190 days to decisionK183311 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k183311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Nov 29, 2018
Decision date	Jun 7, 2019
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ivenix, Inc.
Location	North Andover, MA, US
Contact	John J. Sokolowski
510(k) history	2 submissions · 2 cleared · 2019-2021

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