

K180683 Certa Dose Pediatric Midazolam 5mg/mL IM SyringeNov 7, 2018
237 days to decisionK180683 · Product code: **PQX** · General Hospital
Source: <https://www.510kdatabase.net/k180683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epinephrine Syringe (PQX)
Date received	Mar 15, 2018
Decision date	Nov 7, 2018
Days to decision	237 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Certa Dose, Inc.
Location	Dever, CO, US
Contact	Caleb Hernandez
510(k) history	2 submissions · 2 cleared · 2017-2018

REGULATORY CONSULTANT

Consulting firm	Epstein Becker & Green, P.C.
Contact	James A. Boiani

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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