

**K160589 Certa Dose PD Epinephrine 1mg/mL IM/SC Syringe**Jan 19, 2017  
324 days to decisionK160589 · Product code: **PQX** · General Hospital  
Source: <https://www.510kdatabase.net/k160589/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epinephrine Syringe (PQX)
Date received	Mar 1, 2016
Decision date	Jan 19, 2017
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Certa Dose, Inc.</b>
Location	Dever, CO, US
Contact	SARAH HANSSEN
510(k) history	2 submissions · 2 cleared · 2017-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160589/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026