

**K191313 Unity Subcutaneous Infusion System for Remodulin**Feb 21, 2020  
282 days to decisionK191313 · Product code: **QJY** · General Hospital  
Source: <https://www.510kdatabase.net/k191313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Infusion Pump, Drug Specific, Pharmacy-filled (QJY)
Date received	May 15, 2019
Decision date	Feb 21, 2020
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DEKA Research &amp; Development</b>
Location	Manchester, NH, US
Contact	Jason Demers
510(k) history	3 submissions · 3 cleared · 2016-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191313/> 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