

K190182 Unity Subcutaneous Delivery System for RemodulinMay 6, 2019
94 days to decisionK190182 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k190182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Feb 1, 2019
Decision date	May 6, 2019
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DEKA Research & Development
Location	Manchester, NH, US
Contact	Brian Carney
510(k) history	3 submissions · 3 cleared · 2016-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190182/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026