FDA 510(k) Premarket Notification

K190182 Unity Subcutaneous Delivery System for Remodulin

CLEARED

May 6, 2019
94 days to decision

K190182 · 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