FDA 510(k) Premarket Notification

K191313 Unity Subcutaneous Infusion System for Remodulin

CLEARED

Feb 21, 2020
282 days to decision

K191313 · Product code: **QJY** · General Hospital
Source: https://www.510kdatabase.net/k191313/

SUBMISSION DETAILS

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

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