FDA 510(k) Premarket Notification

CLEARED

K162165 ambIT PCA*PIB, ambIT PIB, ambIT PIB*PCA, ambIT PIEB, and ambIT Programmable Intermittent Pump

Aug 29, 2017
391 days to decision

K162165 · Product code: **MEA** · General Hospital
Source: https://www.510kdatabase.net/k162165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Pca (MEA)
Date received	Aug 3, 2016
Decision date	Aug 29, 2017
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Summit Medical Products, Inc.**
Location	Salt Lake City, UT, US
Contact	LeVoy Haight
510(k) history	4 submissions · 4 cleared · 2011-2017