FDA 510(k) Premarket Notification

K153605 ivWatch Model 400

CLEARED

Feb 11, 2016
56 days to decision

K153605 · Product code: **PMS** · General Hospital
Source: https://www.510kdatabase.net/k153605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Dec 17, 2015
Decision date	Feb 11, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ivwatch, LLC**
Location	Williamsburg, VA, US
Contact	Jaclyn Lautz
510(k) history	6 submissions · 6 cleared · 2015-2024