FDA 510(k) Premarket Notification

CLEARED

K192385 ivWatch Model 400, Device Accessories: Extension Module, SmartTouch Sensor, Patient Cable

Jul 2, 2020
303 days to decision

K192385 · Product code: **PMS** · General Hospital
Source: https://www.510kdatabase.net/k192385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Intravenous (piv) Infiltration Monitor (PMS)
Date received	Sep 3, 2019
Decision date	Jul 2, 2020
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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