FDA 510(k) Premarket Notification

K161916 TelePatch Cardiac Monitor

CLEARED

Dec 21, 2016
162 days to decision

K161916 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k161916/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Jul 12, 2016
Decision date	Dec 21, 2016
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medicomp, Inc.**
Location	Mchenry, IL, US
Contact	Sean Marcus
510(k) history	23 submissions · 23 cleared · 1983-2018