FDA 510(k) Premarket Notification

K182297 Surveyor S2

CLEARED

Jan 24, 2019
153 days to decision

K182297 · Product code: **DRG** · Cardiovascular
Source: https://www.510kdatabase.net/k182297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Physiological Signal, Radiofrequency (DRG)
Date received	Aug 24, 2018
Decision date	Jan 24, 2019
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mortara Instrument, Inc.**
Location	Walker, MI, US
Contact	Marco Manduchi
510(k) history	51 submissions · 51 cleared · 1983-2019