FDA 510(k) Premarket Notification

CLEARED

K190090 DynoSense Vital Sign Measuring System

Aug 2, 2019
197 days to decision

K190090 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k190090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Jan 17, 2019
Decision date	Aug 2, 2019
Days to decision	197 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dynosense Corp.**
Location	Los Gatos, CA, US
Contact	Saeed Azimi
510(k) history	1 submissions · 1 cleared · 2019-2019