FDA 510(k) Premarket Notification

K132077 PATIENT MONITOR

CLEARED

Apr 23, 2014
292 days to decision

K132077 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k132077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 5, 2013
Decision date	Apr 23, 2014
Days to decision	292 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advanced Instrumentations, Inc.**
Location	Hialeah, FL, US
Contact	JORGE MILLAN
510(k) history	16 submissions · 16 cleared · 2009-2017