FDA 510(k) Premarket Notification

K082887 PM-1000F+PATIENT MONITOR

CLEARED

Jan 16, 2009
108 days to decision

K082887 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k082887/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 30, 2008
Decision date	Jan 16, 2009
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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