FDA 510(k) Premarket Notification

K050399 MRI COMPATIBLE PATIENT MONITORING SYSTEM, MODEL 3160

CLEARED

Aug 26, 2005
191 days to decision

K050399 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k050399/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Feb 16, 2005
Decision date	Aug 26, 2005
Days to decision	191 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Research, Inc.**
Location	Orlando, FL, US
Contact	NEIL BATTISTE
510(k) history	14 submissions · 14 cleared · 1989-2005