FDA 510(k) Premarket Notification

CLEARED

K062144 ESCORT M8 VITAL SIGNS PATIENT MONITOR, MODEL 3810

Oct 12, 2006
77 days to decision

K062144 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k062144/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 27, 2006
Decision date	Oct 12, 2006
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Corporation**
Location	Pewaukee, WI, US
Contact	RUSTY KELLY
510(k) history	29 submissions · 29 cleared · 2005-2021