FDA 510(k) Premarket Notification

K061993 EQUIVITAL, MODEL EQ-01

CLEARED

Nov 3, 2006
112 days to decision

K061993 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k061993/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 14, 2006
Decision date	Nov 3, 2006
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hidalgo Limited**
Location	Swavesey Cambridge, GB
Contact	JUSTIN PISANI
510(k) history	2 submissions · 2 cleared · 2006-2012