FDA 510(k) Premarket Notification

K082366 LIFEBED PATIENT VIGILANCE SYSTEM

CLEARED

Sep 26, 2008
39 days to decision

K082366 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k082366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Aug 18, 2008
Decision date	Sep 26, 2008
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hoana Medical, Inc.**
Location	Honolulu, HI, US
Contact	NANCY GERTLAR
510(k) history	5 submissions · 5 cleared · 2006-2010