FDA 510(k) Premarket Notification

CLEARED

K082045 MODIFICATION TO MCARE 300 VITAL SIGNS MONITOR, MODEL 91220

Aug 1, 2008
14 days to decision

K082045 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k082045/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jul 18, 2008
Decision date	Aug 1, 2008
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spacelabs Medical, Inc.**
Location	Hamden, CT, US
Contact	TIM DAVIS
510(k) history	35 submissions · 34 cleared · 1993-2012