FDA 510(k) Premarket Notification

K112877 COMEN MULTI-PARAMETER PATIENT MONITOR

CLEARED

Nov 7, 2012
404 days to decision

K112877 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k112877/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 30, 2011
Decision date	Nov 7, 2012
Days to decision	404 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Goldway Us, Inc.**
Location	San Jose, CA, US
Contact	JIMMY WU
510(k) history	4 submissions · 4 cleared · 2003-2012