FDA 510(k) Premarket Notification

K103791 PHYSIOGLOVE ES WITH ECG ANALYSIS

CLEARED

Oct 21, 2011
298 days to decision

K103791 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k103791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Dec 27, 2010
Decision date	Oct 21, 2011
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Commwell , Ltd.**
Location	Washington, DC, US
Contact	IRVING LEVY
510(k) history	3 submissions · 3 cleared · 2006-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k103791/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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