FDA 510(k) Premarket Notification

K020366 GLOBAL ECG MANAGEMENT SYSTEM (GEMS)

CLEARED

Apr 30, 2002
85 days to decision

K020366 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k020366/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Feb 4, 2002
Decision date	Apr 30, 2002
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiocomm Solutions, Inc.**
Location	Victoria, B.C., CA
Contact	ANGELA HALWAS
510(k) history	9 submissions · 9 cleared · 2002-2019

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k020366/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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