FDA 510(k) Premarket Notification

K082312 PRIME ECG SYSTEM (WITH ENHANCED DIAGNOSTIC ALGORITHM)

CLEARED

Sep 12, 2008
30 days to decision

K082312 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k082312/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Aug 13, 2008
Decision date	Sep 12, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Heartscape Technologies, Ltd.**
Location	Bangor, Co Down, GB
Contact	PAUL PHILLIPS
510(k) history	1 submissions · 1 cleared · 2008-2008