

K082312 PRIME ECG SYSTEM (WITH ENHANCED DIAGNOSTIC ALGORITHM)

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k082312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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