

K100813 QRS CARD S-T SEGMENT ANALYSIS PATIENT MONITORING SYSTEM MODEL: QRS CARD USB

Jul 23, 2010
122 days to decision

K100813 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k100813/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrocardiograph (DPS)
Date received	Mar 23, 2010
Decision date	Jul 23, 2010
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pulse Biomedical, Inc.
Location	Norristown, PA, US
Contact	SALEEM HASAN
510(k) history	3 submissions · 3 cleared · 1998-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k100813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026