

K971650 RHYTHMSTAT XLDec 4, 1997
212 days to decisionK971650 · Product code: **DXH** · CardiovascularSource: <https://www.510kdatabase.net/k971650/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transmitters And Receivers, Electrocardiograph, Telephone (DXH)
Date received	May 6, 1997
Decision date	Dec 4, 1997
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Data Critical Corp.
Location	Bothell, WA, US
Contact	LISA S JONES
510(k) history	9 submissions · 9 cleared · 1997-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971650/> 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 July 3, 2026