

K970367 THERMO-STAT SYSTEMDec 17, 1997
320 days to decisionK970367 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k970367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Jan 31, 1997
Decision date	Dec 17, 1997
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aquarius Medical Corp.
Location	Irvine, CA, US
Contact	W. JEFFREY CHANDLER
510(k) history	3 submissions · 3 cleared · 1995-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970367/> 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 May 21, 2026