

**K061369 TANDEM HEART ESCORT (T.H.E.) CONTROLLER,  
MODEL 5140-8500**

Aug 22, 2006  
97 days to decision

K061369 · Product code: **DWA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k061369/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	May 17, 2006
Decision date	Aug 22, 2006
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cardiacassist, Inc.</b>
Location	Pittsburgh, PA, US
Contact	ROBERT BOLLINGER
510(k) history	21 submissions · 21 cleared · 2000-2024

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k061369/> 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 28, 2026