

**K100585 MEDI-THERM HYPER/HYPOTHERMIA SYSTEM,  
MODELS MTA6900, MTA7900**Jan 20, 2011  
324 days to decisionK100585 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k100585/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Mar 2, 2010
Decision date	Jan 20, 2011
Days to decision	324 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Gaymar Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	BRIAN L ORWAT
Website	<a href="https://www.gaymar.com">https://www.gaymar.com</a>
510(k) history	27 submissions · 27 cleared · 1976-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100585/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026