

**K093694 GERATHERM UNIQUERESC**Sep 20, 2010  
294 days to decisionK093694 · Product code: **DWJ** · CardiovascularSource: <https://www.510kdatabase.net/k093694/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	Nov 30, 2009
Decision date	Sep 20, 2010
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Geratherm Medical AG</b>
Location	Tuttlingen, Baden Wurttemberg, DE
Contact	ANDREA PECSI
510(k) history	2 submissions · 2 cleared · 2010-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093694/> 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 20, 2026