

K051278 GERATHERM SOS-VACUTHERM (THERMAMED SMARTCARE)

Jun 29, 2006
408 days to decision

K051278 · Product code: **DWJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k051278/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Thermal Regulating (DWJ)
Date received	May 17, 2005
Decision date	Jun 29, 2006
Days to decision	408 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rg Ent., Inc.
Location	Southfield, MI, US
Contact	RONALD G LETOURNEAU
510(k) history	3 submissions · 3 cleared · 1996-2006

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Device record: <https://www.510kdatabase.net/k051278/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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