

K001281 GERATHERM BABYWATCH TEMPERATURE MONITORJun 12, 2001
417 days to decisionK001281 · Product code: **FLL** · General Hospital
Source: <https://www.510kdatabase.net/k001281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Apr 21, 2000
Decision date	Jun 12, 2001
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Geratherm AG
Location	Southfield, MI, US
Contact	ED HOLTER
Website	http://www.geratherm.de
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001281/> 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 July 4, 2026